REMARKS

Claims 47 to 85 are in the application. Claims 53, 54, 63, 65- 68, 77, 78 and 84 have been amended to correct minor typographical or clerical errors. Claim 85 has been added. No new matter is believed added.

An updated 1449 form with Applicants copending applications accompanies this paper, along with the most recent office actions in USSN 10/470,438; USSN 10/060,849; USSN 10/470,439; USSN 10/060,603; 10/565,462; USSN 10/895,588 and USSN 11/078,077.

Rejection under 35 USC §103

Claims 47-84 are rejected under 35 USC §103(a) as being unpatentable over Petereit et al. US 2002/0160042 ('042) in view of McAllister et al., US Publication No.: 2003/0068369 ('369). Applicants respectfully traverse this rejection.

Petereit et al. is an application directed to an injection molding method for neutral and acid containing (meth)acrylate copolymers, comprising melting a mixture of a meth)acrylate copolymer and a release agent, with optional additives and which prior to melting devolatizes the mixture while in a thermoplastic state and then injects the molten and devolatized mixture into a mold cavity. The novelty of the Petereit application is the devolatization step. The particular polymers disclosed in the Petereit publication are Eudragit FS (corresponding to Eudragit 4135 in the McAllister '369 publication), Eudragit L or L100-55 grades, Eudragit NE or Eudragit S (see paragraphs 0035-0038 of the '042 specification).

The '042 publication does not teach the specific combination of the Eudragit RL or RS polymers with the required swellable solid as a DME in the amounts as required by Claim 47 herein. The Examiner points to para 0080 as providing for inclusion of other polymers (see below):

[0080] Examples of these other polymers are: polyvinylpyrrolidones, polyvinyl alcohols, cationic (meth)acrylate copolymers made from methyl methacrylate and/or ethyl acrylate and 2-dimethylaminoethyl methacrylate (EUDRAGIT® E100), carboxymethylcellulose salts, hydroxypropylcellulose (HPMC), neutral (meth)acrylate copolymers made from methyl methacrylate and ethyl acrylate (dry matter from EUDRAGIT® NE 30 D), copolymers made from methyl methacrylate and butyl methacrylate (PLASTOID® B) or (meth)acrylate copolymers with quaternary ammonium groups and containing trimethylammonioumethyl methacrylate chloride as monomer (EUDRAGIT® RL and/or EUDRAGIT® RS).

However, the other polymers are in fact the two copolymers which applicants start with, e.g. Eudragit RL or RS. This paragraph is specifically misleading as it includes an error. It states hydroxypropyl cellulose and then puts in brackets (HPMC), hydroxypropylcellulose (HPMC). HMPC is NOT hydroxypropyl cellulose but hydroxypropylmethyl cellulose. Thus the paragraph is indefinite as to which secondary polymer might be included. However as noted, inclusion of these polymers is in addition to the underlying (meth)acrylate copolymer Eudragit FS, Eudragit L, Eudragit NE or Eudragit S.

Para 0080 does not provide for inclusion of multiple additional polymers to the first copolymer, as it does not include a statement of "combinations or mixtures thereof". Thus to get mixture of Eudragit RL or RS and HPC is not a possible combination included within the context of the Petereit publication.

More importantly, Petereit does not suggest a blend of hydroxypropylcellulose polymers having differing molecular weights, as claimed in claims 64 -68. Nor does Petereit add a second dissolution modifying excipient such as claimed in claim 47 and 69.

The McAllister US 2003/0068369 publication is directed to polymeric compositions, which similar to that herein, are injection molded into various parts of a pharmaceutically acceptable dosage form, such as a capsule shell or linker subunit. In contrast to the instant application the claims and specification of the '369 case are directed to use of the polymer Eudragit 4135F, not the polymers Eudragit RL or RS 100 as claimed herein.

While reference in this publication is made to other polymers that might be suitable for use in injection molding process such as the Eudragit RL (Type A) and RS 100 (Type B) as noted by the Examiner in paragraph 0122 it is completely improper and taken out of context of Applicants US 2003/0068369 specification to infer that these copolymers can be used in amounts of 20% or more (Office Action, page 5 last full line). The reference in paragraph 0127 is NOT dependent upon paragraph 0122 but the specific polymers disclosed in US 5,705,189. The polymers disclosed in US 5,705,189 are not Eudragit RS or RL type polymers.

Paragraph 0131 is merely a discussion of other polymers which are insoluble and can hydrate a controllable rate. The discussion which is present in the US 2003/0068369 specification provides no more than is known in the art about these classes of polymers and provides not suggestion or motivation to direct the skilled artisan on how to formulate so that they can actually be used for the article of manufacture as claimed herein.

Cited paragraphs 0136 and 0137 discuss other types of water and water insoluble polymers. It is unclear why the Examiner cites this paragraph as these polymers are not specifically claimed in claim 1 herein.

Each of the polymers, be it Eudragit 4135F, Eudragit E100, or the instant Eudragit RL or RS100 has their own excipient requirements, and processing conditions to make them suitable for extrusion and injection molding into capsule shells or other subunits. The required excipients are not the same, the % w/w amounts of the excipients are not the same, nor are the operating conditions.

More importantly, the end product itself does not function or perform the same way in the human body, other than being a capsule shell suitable for holding a drug substance. They all hydrate, disintegrate and thus disgorge their contents into the gastrointestinal tract at differing rates from each other. Thus these differing compositions provide the means to make the various multicomponent dosage forms

which can be assembled into a final dosage form where the rate of release of the active agent into the gastrointestinal tract can be varied as desired.

US 2003/0068369 specification does not describe an article of manufacture having the specific composition as claimed in Claim 1 herein.

The US 2003/0068369 specification directs the skilled artisan to produce a formulation that has very different characteristics than the product produced by the formulations disclosed in the present application.

The copolymer (referred to as 4135F) in the US 2003/0068369 specification is composed of methyl acrylate, methyl methacrylate and methacrylic acid units, having a molar ratio of these monomer units of 7:3:1. The 4135F polymer is referenced by the manufacturer as being insoluble in acidic media, but dissolves by salt formation above pH 7.0. This is common for a polymer which is used for its enteric properties, e.g. coming off as a coating over a tablet in the colon as opposed to the stomach or the small intestines.

When a compound is said to be pH independent it is meant that the gastric environment does not affect the compound, otherwise they are referred to as pH dependent. The copolymer blend of the US 2003/0068369 specification is no longer governed by the pH of the solution in the gastric tract, but dissolution/disintegration is time controlled release dependent instead. Thus, the US 2003/0068369 specification produces an unexpected result for the blend of 4135F and its excipients resulting in a capsule shell that is not pH dependent.

The Eudragit RS and RL polymers are different than that of the 4135F.

Taking two extracts from the Evonik brochure on Eudragit coatings (shown below), one can readily see that you can have pH independent swellable materials. In other words, they can absorb water from the GI fluids but not necessarily dissolve.

A distinction is made between a 1. Poly(meth)acrylates; soluble in digestive fluids by salt formation EUDRAGIT® L, S, FS and E polymers with acidic or alkaline groups enable pH-dependent release of the active ingredient. **Applications:** from simple taste masking through gastric resistance to controlled drug release in all sections of the intestine

2. Poly(meth)acrylates; insoluble but permeable in digestive fluids EUDRAGIT® RL and RS polymers with alkaline and EUDRAGIT® NE polymers with neutral groups enable controlled time release of the active ingredient by pH-independent swelling. **Applications:** delayed and sustained drug release

Time-Controlled Drug Release

Whether you need your drug to release over a specific period of time or would like to benefit from the advantages of multiparticulate or matrix formulations – EUDRAGIT® can help you achieve your desired release profile. Drug delivery can be controlled throughout the entire gastrointestinal tract to increase therapeutic effect and patient compliance. Different polymer combinations of EUDRAGIT® RL and RS grades allow custom-tailored release profiles to achieve the desired drug delivery performance. EUDRAGIT® NE and NM grades are neutral ester dispersions which do not require addition of plasticizer.

EUDRAGIT® Polymer	Availability	Dissolution Properties
RL 100	Granules	Insoluble
RL PO	Powder	**High permeability**
RL 30 D	30% Aqueous Dispersion	pH-independent swelling
RL 12,5	12.5% Organic Solution	
RS 100	Granules	Insoluble
RS PO	Powder	**Low permeability**
RS 30 D	30% Aqueous Dispersion	pH-independent swelling
RS 12,5	12.5% Organic Solution	
NE 30 D	30% Aqueous Dispersion	Insoluble, low permeability,
NE 40 D	40% Aqueous Dispersion	pH-independent swelling
NM 30 D	30% Aqueous Dispersion	**No plasticizer required** Highly flexible

Looking specifically at the US 2003/0068369 it is stated that the 4135F polymer "in its unformulated state is its high dissolution time, [is] in excess of 30 hours in aqueous media e.g. in SIF (simulated intestinal fluid). Therefore, to improve its dissolution time the polymer is blended with one or more hydrophilic excipients.

This will enhance the absorption of water by the Eudragit 4135F polymer, and so accelerate the rate at which the blended polymer swells on absorption of water."

In contrast, Applicants desired a component which produced an early release capsule or component in a multidosage capsule, (such as in a 2 hour window or less). The polymer Eudragit RL 100 (Röhm), may be extruded into a thin walled component shell by blending with the excipients as claimed herein a coblend of HPC has will produce a stable, injection molded component that can be reliably reproduced and injected from the mold with reduced, or no warpage of the shell. Formulations containing approx. 26% to 63 % HPC's have been found to have similar dissolution times (<2hours) in both simulated gastric fluid and simulated intestinal fluids.

It is necessary to ensure a consistent release of the active agent from the shells or other subcomponents if these are to be used for drug delivery and with other multicomponent dosage forms.

Applicants have determined that the co-blended polymers of the present invention can produce a capsule shell which hydrates and swell considerably more than a non-blended polymeric composition under similar conditions. The present formulations provide for significant improvements in dissolution reproducibility.

As can be seen by the experimental section of the application, formulations with a lubricant, and hydroxypropylcellulose (HPC), or a co-blend of HPC's has now been shown to produce stable, injection molded components which can be reliably reproduced and injected from the mold with reduced, or no warpage of the shell. There is nothing in the cited reference to direct the skilled artisan that specifically HPC or a blend of HPC's would in fact demonstrate this consistency and reproducibility with a completely different polymeric base.

The Examiner seems to be confusing the class of synthetic polymers known as Eudragit as all the same. This is not true. Each of these polymers has their own solubility characteristics ranging from immediate release to time-controlled release to gastroresistant targeting. If you only consider the class of (meth)acrylate copolymers (which is not the entire class of Eudragit's) there are for example (meth)acrylate

copolymers with tertiary ammonia groups, such as the Eudragit E's copolymers. There are (meth)acrylate copolymers with anionic groups, such as Eudragit L100-55, and there are the (meth)acrylate copolymers with quaternary ammonia groups, Eudragit RS and RL. Each of these 3 (meth)acrylate copolymers display very different characteristics from their solubility in gastric juices below 4.0 to those about 5.5 and those which are pH independent, respectively as shown above.

More importantly the resulting rheology of the formulations achieved by the present invention differs from that of Applicants US 2003/0068369 specification.

In view of these remarks, it is believed that there is no necessity for a showing of unexpected results to obviate the obviousness rejection. Because there is no *prima facie* case of obviousness in view of US 2003/0068369 specification., Applicants do not bear the burden of making such a showing at this juncture. Having established that the Office has failed to set forth a *prima facie* case of obviousness, Applicants respectfully request the withdrawal of the §103 rejection to the claims.

Rejection under 35 USC §103

Claims 47-64, 69-77, 82 and 83 are rejected under 35 USC §103(a) as being unpatentable over Petereit et al. US 2002/0160042 ('042) in view of McAllister et al., US Publication No.: 2003/0049311 ('311). Applicants respectfully traverse this rejection.

Applicants incorporate by reference their comments on the Petereit et al., '042 publication above.

The McAllister US 2003/0049311 publication is directed to polymeric compositions, which similar to that herein, are injection molded into various parts of a pharmaceutically acceptable dosage form, such as a capsule shell or linker subunit. In contrast to the instant application the claims and specification of the '369 case are directed to use of the polymer Eudragit E100, not the polymers Eudragit RL or RS 100 as claimed herein.

Similar to that expressed for the rejection over the McAllister '369 publication, the Examiner's comments as they appear on page 9 of the Office Action, 3rd full ¶, are believed to be inaccurate. The statement is shown below as:

> More suitable methacrylic acid copolymers disclosed include Eudragit®RL and/or Eudragit®RS (p. 10, ¶ 0123). The copolymers can be used in amounts of 20% w/w or more (p. 10, ¶ 0125). Preferred polymers disclosed are Eudragit®RL 100. A suggested blend of polymers would be the combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0130).

This statement is the same statement which also appears in the McAllister US2003/0068369 rejection. In the '369 publication the relevant paragraphs are

> **[0125]** More suitably, methacrylic acid copolymers (such as Eudragit E®, Eudragit E100® Eudragit® L and/or Eudragit® S), poly(meth)acrylate copolymers, such as Eudragit® 4135F, and ammonium methacrylate copolymers (such as Eudragit® RL and/or Eudragit® RS), are suitable for injection molding. The group of poly(meth)acrylate copolymers, such as Eudragit® 4135F are a preferred aspect of this invention.
>
> **[0126]** Eudragit E100 is also referred to as butylmethacylat-(2-dimethylaminoethyl)-methacrylat-methylmethacylat-copolymer (1:2:1), is based on (2-dimethylaminoethyl-)methacrylate, butyl methacrylate and methyl methacrylate having a mean molecular weight of about 150,000. It contains not less than 20.8 and not more than 25.5% dimethylaminoethyl groups in the dry substance.
>
> **[0127]** Acrylic and/or methacrylic acid-based polymers which are soluble in intestinal fluids and which can be formed into capsules are for example disclosed in U.S. Pat. No. 5,705,189 (Roehm GmbH) the content of which is incorporated herein by reference in its entirety. These poly-(meth)acrylate copolymers were extrudable and injection molded into capsule half's wherein the ratio of acrylic and/or methacrylic acid was generally 20% w/w or more of the copolymer (Examples 1-8). In these Examples, glycerol monosterate was added on a 3-5% wt base of the polymer as a mold-releasing agent.

It is clear that the reference to the 20% w/w copolymer is specific to the polymers disclosed in the cited reference US 5,705,189. The polymers in US 5,705,189 are Eudragit 4135F, and are not Eudragit RS or RL type polymers as used herein.

There is no teaching or suggestion in the US 2003/0049311 specification to direct the skilled artisan to the specific excipients and the specific % w/w amounts claimed herein to produce multicomponent dosage forms having their specific release rate characteristics. There is direction to the skilled artisan that such components would produce reliable and consistent release rates, nor what those rates would be.

The formulations disclosed in US 2003/0049311 produce capsules that dissolve at a different time frame than those of the US 2003/0068369 and to those claimed herein. The E100 components dissolve within a 17 to 34 minute window, immediately delivering the drug to the stomach contents, not as a controlled release mechanism over a longer time period, such as from 2 to 12 hours (dependent upon the additional excipients added).

The E100 polymeric composition consistently delivers this shortened window when combined with polyethylene oxide, a component which is not even included with the claims of instant application nor disclosed in the specification for use with the RL or RS polymer.

In view of these remarks, it is believed that there is no necessity for a showing of unexpected results to obviate the obviousness rejection. Because there is no *prima facie* case of obviousness in view of US 2003/0068369 specification., Applicants do not bear the burden of making such a showing at this juncture. Having established that the Office has failed to set forth a *prima facie* case of obviousness, Applicants respectfully request the withdrawal of the §103 rejection to the claims.

Obvious Type Double Patenting

The Examiner has provisionally rejected claims 47-84 on the grounds of nonstatutory obviousness type double patenting as being unpatentable over the claims of copending application USSN 10/470,438. Applicants respectfully traverse this rejection.

Application USSN 10/470,438 is directed to dosage forms comprising the copolymer 4135F, similar to that disclosed in the cited McAllister '369 publication herein.

USSN 10/470,438 and USSN 10/060849 (US 2003/0068369) are related applications to each other, but not do not teach the Eudragit RL or RS formulations as claimed herein.

The Examiner has also provisionally rejected claims 47-84 on the grounds of nonstatutory obviousness type double patenting as being unpatentable over the claims of copending application USSN 10/470,439. Applicants respectfully traverse this rejection.

Application USSN 10/470,439 is directed to dosage forms comprising the copolymer E100, similar to that disclosed in the cited McAllister US 2003/0049311 publication herein. USSN 10/470,439 and USSN 10/060,603 (US 2003/0049311) are related applications to each other, but not do not teach the Eudragit RL or RS formulations as claimed herein.

There is a copending related application USSN 11/078,077 as disclosed on Applicants 1449 forms which claims an injection molded and extruded dosage form of Eudragit RL or RS injection molded dosage forms being handled by the same Examiner. That application was filed directly in the US at 12 months, whereas the instant application is a §371 national stage entry application.

In order to advance prosecution on the merits, Applicants submit herewith a terminal disclaimer over the claims of copending application USSN 11/078,077.

In view of these remarks, reconsideration and withdrawal of the provisional rejection to the claims is respectfully requested.

CONCLUSION

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already.

However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/060,849	MCALLISTER ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The 112 rejections of record have been withdrawn in view of applicant's Remarks filed 09/04/09, at pages 23-27.

Claim Rejections - 35 USC § 103

Claims 1, 2, 7-16, 20-22, 39, 40, 73, 74, 81-74, 87-90, 92-95, 112 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189.

Petereit teaches an injection molding composition comprising: a) 45-100% methacrylate copolymer; b) 0.1-3% lubricant; c) 0-50% drier; d) 0-30% plasticizer; e) 0-100% additives or auxiliaries; f) active agent; and g) 0-20% of another polymer or copolymer (paragraphs 0019-0027). Methacrylate copolymer includes 50-70% methyl acrylate, 10-30% methyl methacrylate, and 5-15% methacrylic acid (a 7:3:1 ratio if converted) (paragraph 0038). Plasticizer includes castor oil, sorbitan ester, and polyethylene glycol (paragraphs 0050-0051). Other polymer or copolymer includes polyvinyl pyrrolidone (paragraphs 0078-0080). Petereit further teaches the shape of the molding includes capsule, part of a capsule such as half or a capsule (paragraph 0095). Petereit also teaches the wall thickness of the obtained capsule is of 0.6 mm (paragraph 0101).

Petereit does not explicitly teach the claimed percent amount of lubricant from 5% to about 30%. However, differences in concentration will not support the

patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select a lubricant amount that falls within the claimed range with the expectation of lat least similar result. This is because Petereit teaches the use of the same lubricant, such as stearyl alcohol, for the same purpose, namely, as a mold releasing agent (paragraphs 0041-0044). Further, the use of lubricant as a mold releasing agent in the claimed amount is known in the art. See for example the teaching of Lehmann at column 3, lines 65-67; and example 1. Lehmann teaches the use of 6% of the mold releasing agent, based on the weight of the polymer. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the molding composition of Petereit using lubricant in the claimed amount in view of the teachings of Lehmann.

Petereit further does not teach that the capsule shell composition is substantially pH-independent. It is noted that nowhere in Petereit does the teaching of pH-dependent disclose. Accordingly, the burden is shifted to applicant to show that the capsule composition of Petereit is substantially pH-dependent. This is because Petereit teaches the use of the same polymers and in the same amounts to prepare a composition for the same purpose desired by the applicant, namely, a capsule shell composition useful in pharmaceutical art.

Claims 3-6, 18 and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Bolles US 3,779,942 and Zentner US 4,795,644.

Petereit is relied upon for the reason stated above. Petereit does not expressly teach the use of surfactant.

Bolles teaches a capsule shell composition comprising well known polymer such hydroxypropyl cellulose, and surfactant such as sodium dioctyl sulfosuccinate in an amount of from about 0.001-10% (abstract; and column 2, lines 20-59). Thus, it would have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include surfactant to obtain the claimed invention. This is because Bolles teaches that the addition of surfactant to improve capsule shell storage stability, uniformity and strength (abstract; and column 2, lines 2-8).

Bolles does not teach the claimed surfactant such as sodium dodecyl sulfate. Zentner teaches useful surfactant for wall forming composition includes sodium dodecyl sulfate, and sodium dioctyl sulfosuccinate (column 13, lines 53 through column 14, lines 1-22). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select sodium dodecyl sulfate as a surfactant, because Zentner teaches the equivalency between sodium dodecyl sulfate, and sodium dioctyl sulfosuccinate, and because Zentner teaches the use of sodium dodecyl sulfate in wall forming composition is known in the art.

Claims 1-33, 35, 38-40, 71-97, 112-132 and 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189, Hatano et al. US 6,309,666, and Klug et al. US 3,314,809.

Petereit is relied upon for the reasons stated above. Petereit further does not teach the inclusion of additives such as lactose and mannitol.

Hatano teaches coated capsule compositions comprising a hard outer shell (abstract). The compositions may be formulated for quick release at a desired location in the gastrointestinal tract (column 2, lines 49-62). Suitable materials for the outer shell include methacrylate co-polymers and acrylic co-polymers (column 5, line 42 to column 6, line 23). Each of the components of the capsule, including the hard outer shell, may include various excipients, including binders, disintegrants, lubricants, aggregation-preventing agents, plasticizer, and a surfactant. Excipients include mannitol, lactose and starch. Binders include ethylcellulose, polyvinylpyrrolidone, HPMC, and polyethylene glycol (column 12, lines 1-11). Disintegrants include polyvinylpyrrolidone and hydroxypropylcellulose (column 12, lines 12-17). Lubricants and aggregation-preventing agents include talc, magnesium stearate, and colloidal silicon dioxide. Plasticizers include diethyl phthalate, dibutyl phthalate, and polyethylene glycol. Surfactants include polyoxyethylene sorbitan monooleate, poiyoxyethylene hydrogenated castor oil, and sodium dodecyl sulfate (column 11, line 52 to column 12, line 65). Such additives may be added in any amount within the scope of the knowledge of one of ordinary skill in the art (column 13, lines 3-5). Thus, it would

have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include the excipients in view of the teachings of Hatano. This is because Hatano teaches the use of well known excipients in pharmaceutical art in capsule shell composition, and because Petereit teaches the desirability of using excipients or other auxiliaries known in the art.

It is noted that applicant argues that Petereit teaches the use of HPC in a long list, and there is no motivation to select HPC. However, Klug teaches a capsule shell composition comprising HPC (columns 1-2). Thus, the skilled artisan would have been motivated to select HPC as other polymer for the capsule shell composition of Petereit in view of the teachings of Klug, because Klug teaches that HPC is the stable thermoplastic material for making excellent articles such as capsule shell (column 4, lines 56 through column 5, lines 1-15).

Response to Arguments

Applicant's arguments filed 09/04/09 have been fully considered but they are not persuasive.

Applicant argues that the formulation of the copolymer blend used in the Petereit process does not teach a combination of two (2) dissolution modifying agents as required by claim 1 herein. One of the dissolution modifying excipients for use in the instant invention is a swellable solid. In Petereit, there is no express statement of swellable solids, but use of a second copolymer. The copolymer is an optional excipient in Petereit's blend, being present from 0-20% w/w. Consequently, the resulting blend

does NOT require such an excipient to being present. The list of polymers suitable for use in the Petereit formulation in disclosed in paragraph 0080 shown below. This paragraph provides for a long list of many polymers not claimed or disclosed for use within the context of Applicants invention as a dissolution modifying excipient. Therefore, even if a copolymer is present one would not necessarily be directed to pick and choose as an excipient that one which Applicant describes as a dissolution modifying excipient.

However, in response to applicant's argument that "*[o]ne of the dissolution modifying excipients for use in the instant invention is a swellable solid. In Petereit, there is no express statement of swellable solids, but use of a second copolymer*", it is noted that the "swellable solid" is recited in a Markush group. Thus, at least independent claim 1 does not necessarily require that the "swellable solid" as one of the dissolution modifying excipient in view of the Markush language. Further, in response to applicant's argument that "*the copolymer is an optional excipient in Petereit's blend, being present from 0-20% w/w. Consequently, the resulting blend does NOT require such an excipient to being present*", the Examiner notes that although the excipient is not required, it can be present. The phrase "optional" clearly indicates that it could be present. Moreover the amount of up to 20% indicates that the excipient does present in the blend.

Moreover, in response to applicant's argument that "*the list of polymers suitable for use in the Petereit formulation in disclosed in paragraph 0080 shown below. This paragraph provides for a long list of many polymers not claimed or disclosed for use*

within the context of Applicants invention as a dissolution modifying excipient", it is noted that the list of dissolution modifying excipients recited in claim 1 is broad. See for example "swellable solid" or "water soluble filler".

Applicant argues that in the present invention:

1) the capsule shell and/or linker is meant to break apart at a particular time, and release the contents of the shell/linker to the GI tract at that time, all at once, not over a period of time to provide a controlled constant rate of release;

2) the 4135F polymeric formulations provide for a capsule shell that has a more delayed, or prolonged time period to release the capsule contents into the GI tract; than a gelatin capsule which is of the immediate release;

3) when a multicomponent dosage form of the present invention, is assembled it is possible to have a shell subunit that disperses the contents as an immediate release, and be linked to a second, or third, etc. shell subunit that disperses the contents as pulsitile releases, much later down the GI tract; and

4) prior to the disclosure by Applicants it was not believed possible to prepare a pH-independent **capsule shell or linker itself** using the copolymers as recited in the presently amended claims.

However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the captured features (1) to (4) above) are not recited at least in the rejected independent claim(s). Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

To place the application in condition for allowance, it is suggested to: 1) clarify the dissolution modifying excipients to include specific combination; and 2) incorporate the above captured features 1-4 into all independent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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NOTICE OF ALLOWANCE AND FEE(S) DUE

20462 7590 03/24/2010

GlaxoSmithKline
GLOBAL PATENTS -US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 03/24/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,439	01/20/2004	Stephen Mark MacAllister	P51319	8632

TITLE OF INVENTION: PHARMACEUTICAL FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	06/24/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20462 7590 03/24/2010

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P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,439	01/20/2004	Stephen Mark MacAllister	P51319	8632

TITLE OF INVENTION: PHARMACEUTICAL FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	06/24/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
ROGERS, JAMES WILLIAM	1618	424-451000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,439	01/20/2004	Stephen Mark MacAllister	P51319	8632

20462 7590 03/24/2010

GlaxoSmithKline
GLOBAL PATENTS -US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 03/24/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/470,439	MACALLISTER ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Applicant Arguments/Remarks Made in an Amendment filed 12/11/2009*.

2. ☒ The allowed claim(s) is/are *47,48,50-61,129,130 and 132-137*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 09/09/2009
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dara Dinner on 3/11/2010.

The application has been amended as follows: claims 49,69-76,78-83,85,87-88,90-104,106,108-110,127-128,131 and 138-140 have been canceled.

Claim 47 has been amended as follows:

47. (currently amended) A process for making a pharmaceutical dosage form comprising the steps of:

a) introducing Aminoalkyl Methacrylate Copolymer E present in an amount of about 50 to 90% w/w and an excipient composition comprising at least one dissolution-modifying excipient which is polyethylene oxide present in an amount of about 5 to about 30% w/w; and optionally a second dissolution modifying excipient selected from the group consisting of

i) a swellable solid present in an amount from about 5% to about 60% w/w;

ii) a disintegrant present in an amount of about 5 to 50 % w/w;

iii) a non-reducing sugar present in an amount of about 2.5 to 15% w/w;

iv) a water soluble filler present in the amount of about 5 to 20% w/w;

v) a wicking agent present in the amount of about 2.5% to about 70% w/w;

vi) an inorganic salt present in an amount of 5 to 10% w/w; or a combination or mixture thereof;

and a lubricant present in an amount from 10 to about 25% w/w and optionally a plasticizer from about 0 to 5% w/w and/or a processing agent from about 0 to about 10% w/w; and/or a surfactant present in an amount of about 0.25 to 5% w/w; simultaneously into a first location of an elongated hot melt extruder, the first location having a temperature of about 50°C;

b) mixing said Aminoalkyl Methacrylate Copolymer E and said excipient composition in the hot melt extruder at a temperature ranging from about 50°C to about 125°C to form a homogeneous composition therein and substantially without thermal degradation of the Aminoalkyl Methacrylate Copolymer E and the excipient composition;

(c) extruding the homogeneous composition in the form of a strand from the hot melt extruder though a die at a second location distal from said first location, said second location having a temperature not greater than about 125°C;

c) cutting the strand into pellets; and

d) introducing said pellets into an injection molder and forming a thin-walled capsule shell compartments from said pellets by injection molding, and wherein the shell between and including the inner and outer surfaces of said shell is composed of the extruded and injection molded capsule shell composition.

In claim 48 line 3, the recitation of "croscarmellose sodium," has been deleted.

In Claim 133 line 2, the recitation of "10 to 20" has been deleted and replaced with "5 to 30".

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/895,588	07/21/2004	Stephen Mark McAllister	PU60404	7883

7590 07/08/2010

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
07/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/895,588	MCALLISTER ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35-46,48-51,53,54,56,57 and 76-94* is/are pending in the application.

4a) Of the above claim(s) *6,13,26,27,30,31,33,36,76-80,83 and 85-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12,14-25,28,29,32,35,37-46,48-51,53,54,56-61,64-75,81,82,84, and 89-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants': amendment to the claims, amendment to the specification, and remarks, filed on 27 February 2010.
- The 35 USC 112, second paragraph rejection is withdrawn in view of the amendment.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-12, 14-25, 28, 29, 32, 35, 37-46, 48-51, 53, 54, 56-61, 64-75, 81, 82, 84, and 89-94 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0160042 ("Petereit"), in view of U.S. Patent No. 6,270,797 ("Gidwani"), further in view of U.S. Patent No. 6,139,875 ("Adams"), further in view of U.S. Patent No. 3,779,942 ("Bolles"), further in view of U.S. Patent No. 4,795,644 ("Zentner"), further in view of U.S. Patent No. 4,564,363 ("Bagnall") further in view of U.S. Patent No. 6,387,401 ("Rosenberg").

Petereit reference teaches injection-molded capsules, which may comprise methacrylate copolymers composed of from 50% to 70% by weight of methyl acrylate, 10 to 30% by weight of methyl methacrylate, and 5% to 15% by weight of methacrylic acid (see abstract and p. [0038]). The ratio of free carbosyl groups to ester groups of

1:10 is inherent to the disclosed polymers. The capsule may include other components, such as a release agent, a plasticizer, additives or auxiliaries, pharmaceutical agents, and other polymers or copolymers (see abstract). Plasticizers such as triethyl citrate and tributyl citrate may be included in amounts ranging up to about 30% by weight (see p. [0049] to [0051]). Polymers such as hydroxypropyl cellulose and polyvinylpyrrolidones may be included in amounts of up to 20% by weight (see p. [0078] to [0080]). The processing of the ingredients takes place in an extruder in a temperature ranging from 120°C to 250°C (see p. [0030]). In one embodiment, the mixture is processed in a twin-screw extruder, with the resulting extrudate bring chopped to give pellets (see [0099]). The molded capsules may be joined by various methods including adhesive bonding, welding by laser, ultrasound or microwaves, or by means of a snap connection (see p. [0095]). In one embodiment, a capsule with a wall thickness of 0.6 mm is produced (see p. [0101]).

Petereit differs from the instant application in that it does not explicitly teach at least two hydroxypropyl cellulose polymers having a differing molecular weight.

Gidwani teaches a matrix system for sustained release of an active agent (see col. 3, lines 51-53). The system comprises use of mixtures of ydrophilic polymers such as hydroxypropyl cellulose (KLUCEL) (see col. 3, lines 53-61, example 4). The molecular weight of hydroxypropyl cellulose is disclosed at a range of 80,000 to 115,000 (see col. 4, lines 1-3). A combination of the different molecular weights of the same polymer and/or different molecular weights of the same polymer and/or different polymers may be employed (see col. 4, lines 3-5). Gidwani explains that use of

hydrophilic polymers in sustained release systems is important to achieve approximately zero-order release over a prolonged period of time by achieving proper erosion of the matrix and dissolution (see col. 3, lines 14-27).

The Petereit reference does not teach the inclusion of lubricants or processing agents in the concentrations being claimed instantly.

Adams teaches an enteric composition comprising an enteric polymer, about 5 to 45 weight percent of a hydrophobic compound such as stearyl alcohol, and about 5 to 50 weight percent of a water-insoluble flake material such as talc (see col. 8, examples 1-8; and claims 1-5). Such additives allow for the enteric composition to achieve superior material and release properties (see col. 2, lines 41-65).

The Petereit reference differs from the instant application in that it does not teach a surfactant in the concentrations being claimed instantly.

Bolles teaches a capsule shell composition (see col. 1, lines 34-45). The disclosed composition comprises, *inter alia*, surfactants at a concentration of 0.001-10% (see col. 2, lines 17-21). Bolles explains that inclusion of surfactant in the shell composition considerably increases the shelf, storage, or half-life of the capsules (see col. 2, lines 2-6). Disclosed surfactants include hydrocarbon surfactans such as sodium dioctyl sulfosuccinate sodium carboxymethyl cellulose, and polyoxyethylene polyol fatty acid esters (see col. 2, lines 53-57). Bolles does not disclose sodium dodecyl sulfate as a surfactant, however use of sodium dodecyl sulfate in oral dosage forms was known in the art at the time the instant application was filed, as evinced by Zentner (see col. 14, line 13).

The Petereit reference differs from the instant application in that it does not a dissolution modifying disintegrant in the concentrations being claimed.

Bagnall teaches a capsule-like container comprising an outer-wall comprised of a biodegradable polymeric material (see col. 2, lines 30-35). Disintegrants such as sodium starch glycolate are also disclosed (see col. 2, line 66) at a concentration of 2-10% (see col. 3, line 1).

The Petereit reference differs from the instant application in that it does not disclose an absorption enhancer. However, use of absorption enhancers, such as lechithin, in extruded pharmaceutical compositions was known in the art at the time the instant application was filed, as shown by Rosenberg (see claims 1 and 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a capsule composition comprising a copolymer of methyl acrylate, methyl methacrylate and methacrylic acid, at least two hydroxypropyl cellulose polymers, a lubricant, a dissolution modifying excipient, a surfactant, a plasticizer, a processing agent, and an absorption enhancer, as taught by Petereit, in view of Gidwani, further in view of Adams, further in view of Bolles, further in view of Zenter, further in view of Bagnall, further in view of Rosenberg. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in an injection molded composition with high mechanical strength and high heat resistance, as explained by Petereit. Addition of hydroxypropyl cellulose polymers is important to achieve approximately zero-order release over a prolonged period of time by achieving proper erosion of the matrix and dissolution, as

explained by Gidwani. Addition of a lubricant such as steryl alcohol and a processing agent such as talc allow for the enteric composition to achieve superior material and release properties, as explained by Adams. Addition of surfactant in the shell composition considerably increases the shelf, storage, or half-life of the capsules, as explained by Bolles. See above.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-12, 14-25, 28, 29, 32, 35, 37-46, 48-51, 53, 54, 56-61, 64-75, 81, 82, 84, and 89-94 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application Nos. 10/060,603; 10/060,849; 10/470,439; 10/565,462; 11/078,077; and 10/519,158.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the each of the

above-cited copending applications claim similar subject matter. For example, Application No. 10/060,603 ("'603") claims a capsule comprising a shell being composed of an extruded and injection molded capsule shell composition comprising aminoalkyl methacrylate copolymer E (30-90%), a lubricant (0-30%), at least one dissolution modifying excipient (5-70%), a plasticizer (0-5%), and a processing agent (0-10%) (*see* claim 1). '603 does not claim at least two hydroxypropyl cellulose polymers, however Gidwani teaches a matrix system for sustained release of an active agent comprising use of mixtures of ydrophilic polymers such as hydroxypropyl cellulose (KLUCEL). The molecular weight of hydroxypropyl cellulose is disclosed at a range of 80,000 to 115,000 (see above). Thus, the compositions recited in the claims of the copending applications listed above are directly within the scope of the compositions of the instant claims.

This is a genus-species situation, wherein the numerous species of the copending application claims are directly within the scope of the large genus of the pending claims, thereby creating an 'anticipation situation' in obvious type double patenting.

There are numerous applications that may necessitate a double patenting rejection due to the breadth of the claims, as can be seen by an inventors name search of US Patents and Applications. It would constitute an undue burden for the Examiner to specifically analyze each of the numerous patent applications. A quick search turned up the copending applications above that appear to have similar subject matter as claimed. The Examiner requests a complete list of both patents and pending

applications, which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicants' arguments filed on 27 February 2010 have been fully considered but they are not persuasive.

Applicants argue that Petereit does not teach a combination of a blend of two hydroxypropyl cellulose polymers, each having different molecular weights. See remarks, pages 31-33.

Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Gidwani was cited for this teaching (see substantive rejection, above).

Applicants argue that a second copolymer is an optional excipient in Petereit. See remarks, page 31.

The applicants' arguments are based on what the examiner believes to be a narrow interpretation of the prior art. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843

(Fed. Cir.), *cert. Denied*, 493 U.S. 975 (1989). It is the position of the examiner that one of ordinary skill in the art, given both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

Applicants argue that even if a copolymer is present one would not necessarily be directed to pick and choose as an excipient that one which Applicant describes as two HPC's of different molecular weight. See remarks, paragraph bridging pages 31 and 32.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). MPEP 2144.06.

Additionally, as indicated above, Gidwani was cited for this teaching.

Applicants argue that Gidwani is non-analogous art. See remarks, page 34.

Examiner respectfully submits that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Gidwani and Petereit share the same field of endeavor.

Applicants argue that Adams teaches amounts of talc that exceed that of applicants' claim 1. See remarks, page 36.

Adams teaches 5-50% talc (see claims 1-5). Instant claim 1 recites lubricant amount of 10-25%. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Applicants argue that Petereit specifically reduced the amount of mold release agent needed in the formulation. See remarks, page 36.

Examiner respectfully submits that the reduced amount taught my Petereit may be within the 10-25% claimed instantly. In any event, Adams teaches a lubricant concentration which overlaps with that claimed instantly (see above).

Applicants argue that Adams does not use the word "release" in the same way as the instant application. See remarks, page 37.

It is the position of the examiner that one of ordinary skill in the art, given both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. *See* MPEP § 2111 and 2123.

Applicants argue that the temperature and pressures needed to extrude and injection mold the shells and linker subunits herein is not the same as that of the encapsulation process of the '942 patent. See remarks, page 38.

The processes of extrusion and injection molding are not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicants argue that the '942 patent does not produce a "subunit". See remarks, page 39.

The plurality of subunits is deemed to be a matter of engineering design choice, and thus does not serve to patentably distinguish the claimed subject matter over the prior art. *In re Kuhle*, 526 F. 2d. 553, 188 USPQ 7 (CCPA 1975).

Applicants argue that the goal of Zenter is to deliver to the GI tract a drug at a substantially constant rate. See remarks, page 40.

The difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. Denied, 500 U.S. 904 (1991) ... ."

Applicants argue that there is no teaching, suggestion, or motivation to combine Petereit with Gidwani, Adams, Bolles, or Zentner. See remarks, page 41.

Examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). As indicated above, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been

individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). MPEP 2144.06.

Regarding the provisional obviousness-type double patenting rejections, applicants argue that the rejection is unclear as to why the claims are not patentably distinct. See remarks, page 45.

As indicated in the rejection, this is a genus-species situation, wherein the numerous species of the copending application claims are directly within the scope of the large genus of the pending claims, thereby creating an 'anticipation situation' in obvious type double patenting.

There are numerous applications that may necessitate a double patenting rejection due to the breadth of the claims, as can be seen by an inventors name search of US Patents and Applications. It would constitute an undue burden for the Examiner to specifically analyze each of the numerous patent applications. A quick search turned up the copending applications above that appear to have similar subject matter as

claimed. The Examiner requests a complete list of both patents and pending applications, which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,462	01/20/2006	Stephen Mark McAllister	PU60404	9920

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GlaxoSmithKline
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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
07/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,462	MCALLISTER ET AL.	
	Examiner	Art Unit	
	S. TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2010*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-41 and 44-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *37-41 and 44-106* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 37-41 and 44-70 are drawn to a multi-component dosage form, classified in class 424, subclass 489.

II. Claims 71-106 are drawn to a capsule dosage form, classified in class 424, subclass 451.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related product. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, and function. See for example, the product of Group I does not require the outer and the opposed inner surface of Group II. Similarly, the product of Group II does not require that the drug substance-containing capsule compartment is soluble or disintegrable in a patient's gastro-intestinal environment.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species:

1) solid matrix comprising at least two hydroxypropyl cellulose polymer, please select a single species from claims 38-40 and from Markush Group in claims 66 or 74-77;

2) lubricant: please select from Markush Group recited in claim 41;

3) at least one dissolution modifying excipient, please select a single species from: a) disintegrant, b) swellable solid, c) non-reducing sugar, d) water soluble filler, 3) wicking agent, or f) an inorganic salt;

4) if disintegrant is selected, please select a single species from Markush Group of claim 46 or 81;

5) if swellable solid is selected, please select a single species from claim 50 or 85;

6) plasticizer: please select a single species from claim 53 or 88;

7) absorption enhancer: please select a single species from claim 56 or 91;

8) surfactant: a) sodium dodecyl sulphate, or b) block copolymer of ethylene oxide and propylene oxide;

9) second dissolution modifying excipient: a) wicking agent, b) sodium starch glycollate, or c) croscarmellose sodium;

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 37 and 71 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

No telephone communication was made because the requirement for restriction is complex.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/078,077	03/11/2005	Adrian Brown	PU60746	8251

7590 03/31/2010

GLAXOSMITHKLINE
Corporate Intellectual Property- UW2220
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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
03/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/078,077	BROWN ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-12,14-27,29-40 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-12,14-27,29-40 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response, Amendment and Applicant's Arguments/Remarks after Non-Final Office Action, all filed 08/03/09 and 12/18/09 is acknowledged.

Applicant has overcome the following objection(s) and/or rejection(s) by virtue of the amendment to the claims and/or persuasive remarks: (1) The claim objections for claims 17 and 40 have been withdrawn; (2) The 35 U.S.C. §112, second paragraph rejection of claims 14, 17, 30, 32 and 36 have been withdrawn; (3) The 35 U.S.C. §102(e) rejections of claims 1-43 over McAllister (U.S. Pat. Pubn. No. 2003/0068369); McAllister (U.S. Pat. Pubn. No. 2003/0049311) and Clarke (U.S. Pat. No. 7,163,693) have been withdrawn; (4) The U.S.C. §103(a) rejection of claims 1-43 over Berndl (U.S. Pat. Pubn. No. 2004/0013697) has been withdrawn.

Claims 1-7, 9-12, 14-27, 29-40 and 48 are pending in this action. Claims 1-4, 9, 11, 14-21, 27, 29, 30, 32, 34-37 and 40 have been amended. New claim 48 has been added. Claims 8, 13, 28 and 41-47 have been cancelled. Claims 1-7, 9-12, 14-27, 29-40 and 48 remain rejected.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "*the dosage form of claim 2, wherein the lubricant is stearyl alcohol...*" in lines 1-2, respectively. There is insufficient antecedent basis for this limitation in the claim. (Claim 2 from which claim 12 depends does not reference any "lubricant").

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9-12, 14-27, 29-40 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAllister *et al.* (hereinafter "McAllister") (U.S. Pat. Appln. Pubn. No. 2003/0068369).

McAllister ('369) teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form (see Abstract). Also disclosed are injection-molded capsule shells, linkers, spacers, multi-component injection molded capsule shells, linkers, spacers and multicomponent dosage forms (page 1, ¶ 0007 & 0012). These limitations read on a "capsule having a shell…the shell being composed of an extruded and injection molded composition".

Polymers suitable for injection molding include PEO, PEG, mixtures of PEO & PEG, PVA, PVP, cellulose derivatives such as hydroxypropyl cellulose, hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, starch and its derivatives, sodium starch glycolate, polysaccharides such as chitosan, polyacrylates and poly(meth)acrylates and its derivatives such as the Eudragit® family of polymers and combinations and mixtures thereof (p. 9, ¶ 0122).

More suitable methacrylic acid copolymers disclosed include Eudragit®RL and/or Eudragit®RS (p. 10, ¶ 0125). The copolymers can be used in amounts of 20% w/w or more (p.

10, ¶ 0127). Preferred polymers disclosed are Eudragit®RL 100. A suggested blend of polymers would be the combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0131).

Water soluble and water-insoluble polymers are discussed at p. 10, ¶ 0136-0137).

The polymer material includes substances which modify their properties, such as: lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like (p. 11, ¶ 0142). Specific substances are disclosed at page 11, (p. 11, ¶ 0143 - p. 12 ¶ 0156). These substances (lubricant - i.e., stearyl alcohol; surfactant; plasticizers, etc.) are the same as those claimed by Applicant. Lubricants are disclosed in amounts of from about 0 to about 30% w/w (p. 12, ¶ 0154). Suitable amounts of dissolution modifying agents (i.e., disintegrants) are about 10% to 40% as well as 10% to 70% for swellable solids such as hydroxypropylcellulose (p. 12, ¶ 0152).

With regards to the amounts and/or ranges being claimed, it is the position of the Examiner that suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regards to new claim 48, which recites that the "capsule shell has a wall with a thickness in the range of about 0.1-0.8 mm", McCallister meets this limitation. McCallister

teaches at page 3, paragraph [0024], that the "side wall of the capsule is composed of a plurality of panels, each having a thickness in the range of about 0.2 to 0.3 mm". This capsule shell thickness range reads on and overlaps with Applicant's claimed range. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of McCallister. McCallister explicitly teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms. The prior art teaches formulations as are instantly claimed that comprise the same ingredients, in similar amounts and produced in the same manner (i.e., injection-molding) as that desired and sought by Applicant.

* * * * *

Claims 1-7, 9-12, 14-27, 29-40 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAllister *et al.* (hereinafter "McAllister") (U.S. Pat. Appln. Pubn. No. 2003/0049311).

McAllister ('311) teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form

(see Abstract). Also disclosed are injection-molded capsule shells, linkers, spacers, multi-component injection molded capsule shells, linkers, spacers and multicomponent dosage forms (page 1, ¶ 0007 & 0012).

Polymers suitable for injection molding include PEO, PEG, mixtures of PEO & PEG, PVA, PVP, cellulose derivatives such as hydroxypropyl cellulose, hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, starch and its derivatives, sodium starch glycolate, polysaccharides such as chitosan, polyacrylates and poly(meth)acrylates and its derivatives such as the Eudragit® family of polymers and combinations and mixtures thereof (p. 9, ¶ 0120).

More suitable methacrylic acid copolymers disclosed include Eudragit®RL and/or Eudragit®RS (p. 10, ¶ 0123). The copolymers can be used in amounts of 20% w/w or more (p. 10, ¶ 0125). Preferred polymers disclosed are Eudragit®RL 100. A suggested blend of polymers would be the combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0130).

Water soluble and water-insoluble polymers are discussed at p. 10, ¶ 0135-0136). The polymer material includes substances which modify their properties, such as: lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like (p. 11, ¶ 0141). Specific substances are disclosed at page 11, (p. 11, ¶ 0143 – p. 12 ¶ 0160). These substances (lubricant - i.e., stearyl alcohol; surfactant; plasticizers, etc.) are the same as those claimed by Applicant. Lubricants are disclosed in amounts of from about 0 to about 30% w/w (p. 12, ¶ 0155). Suitable amounts of dissolution modifying agents (i.e., disintegrants, swellable solids) are provided in amounts of from about 2.5% to 70% w/w (p. 11, ¶ 0146).

With regards to the amounts and/or ranges being claimed, it is the position of the Examiner that suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regards to new claim 48, which recites that the "capsule shell has a wall with a thickness in the range of about 0.1-0.8 mm", McCallister meets this limitation. McCallister teaches at page 3, paragraph [0024], that the "side wall of the capsule is composed of a plurality of panels, each having a thickness in the range of about 0.2 to 0.3 mm". This capsule shell thickness range reads on and overlaps with Applicant's claimed range. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of McCallister. McCallister explicitly teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms. The prior art teaches formulations as are instantly claimed that comprise the same ingredients, in similar amounts and produced in the same manner (i.e., injection-molding) as that desired and sought by Applicant.

* * * * *

Claims 1-7, 9-12, 14-27, 29-40 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke *et al.* (hereinafter "Clarke") (U.S. Patent No. 7,163,693).

Clarke ('693) teaches a multi-component pharmaceutical dosage form comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form (see Abstract).

Polymers suitable for injection molding include PEO, PEG, mixtures of PEO & PEG, PVA, PVP, cellulose derivatives such as hydroxypropyl cellulose, hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, starch and its derivatives, sodium starch glycolate, polysaccharides such as chitosan, polyacrylates and poly(meth)acrylates and its derivatives such as the Eudragit® family of polymers and combinations and mixtures thereof. Particularly suitable methacrylic acid copolymers disclosed include Eudragit®RL and/or Eudragit®RS (column 10, lines 42-57); (col. 11, lines 3-19).

The polymer material includes substances which modify their properties, such as: lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like (col. 11, lines 20-36).

With regards to the amounts and/or ranges being claimed, it is the position of the Examiner that suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are

variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regards to new claim 48, which recites that the "capsule shell has a wall with a thickness in the range of about 0.1-0.8 mm", Clarke meets this limitation. Clarke teaches at column 8, lines 15-23 that the "wall of the capsule compartment is preferably 0.1-0.8 mm thick". This capsule shell thickness range of Clark reads on and exactly overlaps with Applicant's claimed range. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Clarke.

* * * * *

Pertinent Art:

Prior art, made of record, cited of interest and deemed relevant by Examiner:

U.S. Patent Nos: 6,284,803; 6,318,650; 6,517,866; 6,797,283.

* * * * *

Response to Arguments

Applicant's arguments filed 08/03/09 have been fully considered and were found to be partially persuasive.

- **Claim Objections:**

Applicant argued, "While Applicants disagree with the Examiner, claims 17 and 40 have been amended accordingly."

This was found persuasive, based on the amendment to the claims. Accordingly, the claim objections for claims 17 and 40 have been withdrawn.

- **Claim Rejections - 35 USC § 112:**

Applicant argued, "Claim 14 has been amended to remove the terminology of or other hydroxyalkylcellulose derivative".

Applicant argued, "For claims 17, 30 and 32, claim 17 has been amended to depend upon claim 16; claim 28 has been added to claim 27 and the claim dependencies of claims 30 and 32 are appropriately corrected."

Applicant argued, "Claim 36 has been amended to remove the abbreviation of HPC".

These arguments were found persuasive, based on the amendment to the claims. Accordingly, the 35 U.S.C. §112, second paragraph rejection of claims 14, 17, 30, 32 and 36 have been withdrawn.

- **Claim Rejections - 35 USC § 102(e) over McCallister ('369):**

Applicant argued, "In contrast to the instant application, the claims and the specification of the '369 case are directed to the use of the polymer Eudragit 4135F, not the polymers Eudragit RL or RS100 as claimed herein, which are generally referred to as Aminoalkyl Methacrylate

Copolymers. A key functionality of both of these polymers is that they are pH independent. In contrast, the 4135F polymer is pH dependent at pH>7.0. The '369 publication does not disclose the inclusion of Eudragit RL100 or RS100 present in an amount of about 10 to about 80%."

Applicant's arguments have been considered and were found persuasive. Accordingly, the 35 U.S.C. §102(e) rejection of claims 1-43 over McAllister ('369) has been withdrawn.

However, this rejection has now been reformulated as a 35 U.S.C. §103(a) rejection. The McCallister '369 reference is suggestive of the teaching of the use of the polymers - Eudragit®RL and/or Eudragit®RS as claimed (p. 10, ¶ 0125). The reference is also suggestive of blends of polymers comprising a combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0131). While the reference prefers to utilize Eudragit 4135F, the Examiner points out that Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). In addition, whilst McCallister does not explicitly teach the claimed amounts and/or ranges, it remains the position of the Examiner suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

- **Claim Rejections - 35 USC § 102(e) over McCallister ('311):**

Applicant argued, "The '311 publication is directedto the use of the copolymer Eudragit E100 and does not disclose the inclusion of Eudragit RL100 or RS100 present in an amount of about 10 to about 80%."

Applicant's arguments have been considered and were found persuasive. Accordingly, the 35 U.S.C. §102(e) rejection of claims 1-43 over McAllister ('311) has been withdrawn.

However, this rejection has now been reformulated as a 35 U.S.C. §103(a) rejection. The McCallister '311 reference is suggestive of the teaching of the use of the polymers - Eudragit®RL and/or Eudragit®RS as claimed (p. 10, ¶ 0123). The reference is also suggestive of blends of polymers comprising a combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0130). With respect to the claimed amounts and/or ranges, as delineated above, the determination of suitable or effective amounts is within the level of the skilled artisan. See *In re Aller*. Applicant argues that "McCallister (in paragraph 0123) does not teach how one formulates such a polymer to injection mold it, nor what specific excipients and amounts are necessary. This argument was not deemed convincing. Note in particular that McCallister explicitly teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the

assembled dosage form by a weld between parts of the assembled dosage form (see Abstract). The reference also teaches injection-molded capsule shells, linkers, spacers, multi-component injection molded capsule shells, linkers, spacers and multicomponent dosage forms (page 1, ¶ 0007 & 0012). Thus, the reference vividly teaches injection molded formulations (i.e., capsules) as claimed. The reference further teaches use of the same components (lubricant - i.e., stearyl alcohol; surfactant; plasticizers, etc.) as that claimed by Applicant. The reference further discloses suitable amounts of dissolution modifying agents (i.e., disintegrants, swellable solids) provided in amounts of from about 2.5% to 70% w/w (p. 11, ¶ 0146). Hence, the prior art teaches injection molded capsules comprising the formulation excipients as claimed herein by Applicant. Applicant's argument that "Injection molded articles with such polymers is not the novelty of the present invention and that it is the specific formulations that provide for consistent release of the article from the mold and for use in humans as a capsule component" was not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., consistent release of the article from the mold) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this regard, the claims are entirely silent in terms of any reference to release, rates of release or dissolution profiles. Thus, Applicant's arguments are not commensurate in scope with the claims, which do not require "consistent release" as argued herein by Applicant.

- **Claim Rejections - 35 USC § 102(e) over Clarke ('693):**

Applicant argued, "The '693 patent is directed to the underlying multicomponent dosage forms which the '311 and '369 and the instant application all form the compositions of. The '693 patent does not provide the specifics of the claimed invention herein."

Applicant's arguments have been considered and were found persuasive. Accordingly, the 35 U.S.C. §102(e) rejection of claims 1-43 over Clarke ('693) has been withdrawn.

However, this rejection has now been reformulated as a 35 U.S.C. §103(a) rejection. The Clarke reference as noted, above, teaches a multi-component pharmaceutical dosage form comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form (see Abstract). The reference also teaches polymers suitable for injection molding. Particularly suitable methacrylic acid copolymers are disclosed and include Eudragit®RL and/or Eudragit®RS (column 10, lines 42-57); (col. 11, lines 3-19). The further addition of lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like is also discussed (col. 11, lines 20-36). With respect to the claimed amounts and/or ranges, as delineated above, the determination of suitable or effective amounts is within the level of the skilled artisan. See *In re Aller*.

- **Claim Rejections - 35 USC § 103(a) over Berndl ('697):**

Applicant argued, "Berndl is directed to self-emulsifying formulations; the present application is not a self-emulsifying formulation."

Applicant's arguments have been considered and were found persuasive. Accordingly, the U.S.C. §103(a) rejection of claims 1-43 over Berndl (U.S. Pat. Pubn. No. 2004/0013697) has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

- No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

March 26, 2010

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,603	01/30/2002	Stephen Mark McAllister	P51319	8276

7590 06/04/2010

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No.	Applicant(s)	
	10/060,603	MCALLISTER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on *09 April 2010* is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
- ☐ B. New paragraph(s) should not be underlined.
- ☐ C. Other _____.

☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
- ☐ B. Other _____.

☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
- ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
- ☐ C. Other _____.

☐ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
- ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
- ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
- ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
- ☒ E. Other: *See Continuation Sheet*.

☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):
_____

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.

2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

   Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

   Failure to timely respond to this notice will result in:
   Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or
   Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

/Blessing M. Fubara/ Primary Examiner, Art Unit 1618	

Notice of Non-Compliant Amendment (37 CFR 1.121)

Continuation of 4(e) Other: Claim 1 filed 9/17/09 had "selected from" so that the phase is not a new addition to the claim 1 as indicated by the underlining in the current amendment; claim 22 has the status identifier of "withdrawn/amended" but the claim is not currently amended; the status identifier for claims 77-79, 83, 90, 114 and 115 should be ---withdrawn/previously amended--- because these claims were amended on 9/17/09 .

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,603	01/30/2002	Stephen Mark McAllister	P51319	8276

7590 10/06/2009

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/060,603	MCALLISTER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *17 September 2009*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: See *Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-13, 23, 26-28, 108-111, 117-120 and 126*.
   Claim(s) withdrawn from consideration: *14-22,24,25,69-102,105,106,112-116 and 121-125*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 9/9/2009
13. ☒ Other: See Continuation Sheet.

/Blessing M. Fubara/
Examiner, Art Unit 1618

Continuation of 3. NOTE: Amendment to claim 1 indicating that the lubricant is no longer optional, including wicking agent, inorganic salt, lactose, and non-reducing sugar to the composition of claim 1 requires further consideration and search and the amendment are not deemed to place the claims in condition for allowance .

Continuation of 11. does NOT place the application in condition for allowance because: a) applicant's argument that the provisional obviousness type double patenting rejection is improper because the current claims are the subject of restriction requirement in the co-pending application 10/470,439 does not overcome the rejection, i) the provisional rejection is maintained because the claims are not allowable over the prior art and ii) this application was not filed as a divisional application of 10/470,439 and in fact, the application has not claimed priority for 10/470,439.

b) Applicant's arguments that Hatano does not teach the limitations of the claims are not persuasive because Hatano teaches lubricants, binders and EUDRAGIT E 100 coated capsules (see column 6, lines 1-12; column 9, lines 51-65; column 10, line 65 to column 11, line 4; column 12, lines 1-34). While Hatano does not teach the exact percent amounts of these polymers, the artisan in formulating the capsule of Hatano would use appropriate amounts suitable for the capsule formulation. Lubricant, plasticizers and processing agents are optional in claim 1. The rejection was based on combination of references with Hay teaching that the polyethylene glycol or polyethylene oxide or polyvinylpyrrolidone-vinylacetate copolymers are known binders, and Grief teaching hard capsules to comprise of stearyl alcohol lubricant. Hatano teaches the capsule shell to comprise 48% EUDRAGIT E 100 in Example 1 at column 16 and that intersects the amount of the EUDRAGIT in the range of 30-90% recited in claim 1. Therefore, contrary to applicant's suggestion, Hatano teaches EUDRAGIT E 100 in an amount of 48%; Lubricant and plasticizer is optional in claim 1, but the Hay and Grief provide what is missing in Hatano. Applicant is arguing against the Hatano art separately when the rejection was made over combination of references.

c) With regards to the presence of a second excipient in the capsule shell of claim 7, it is noted that Hatano further coats the EUDRAGIT shell with HPMCAS or hydroxypropylmethylcellulose (Examples 1 and 3) with the hydroxypropylmethylcellulose meeting the limitations of claim 7.

d) With regards to claim 108, the artisan in formulating the capsule would use specific amounts that would lead to the desired release and in fact, in Hatano, the hydroxypropylmethylcellulose is at 24%, which is a point within the recited range of 5-60%.

e) injection molding and extrusion and processes of making the coating are processes of making the product and does not patentably distinguish the capsule of the claim from the capsule of the prior art.

f) Applicant's argument that the claimed capsule shell is not the layered capsule of Hatano's claims and that the capsule is coated in Hatano is not persuasive to overcome the rejections and place the claims in condition for allowance because, Hatano is not limited to the claims but the whole document is evaluated for what it teaches and the comprising language of the claims is open and does not exclude layers.

g) The amendment filed after prosecution is closed has not been entered and applicant's argument regarding the amendment after final is therefore moot.

h) Applicant argues that the capsule composition of Hatano is a control and delay release product while the product of the claim is an immediate release dosage form that dissolves within 17-34 "minute window" as shown in Figure 2. The examiner disagrees with the applicant that the claimed capsule is immediate release and the capsule of Hatano is a delayed or sustained release because applicant has not limited the claims to immediate release. Also, applicant's specification contemplates immediate release, sustained release and pulse release units (see paragraphs [0018], [0046] of the published application). Furthermore, Figure 2 of the specification is a demonstration of the dissolution profile of polymeric compositions (see paragraph [0028] of the published application) and not comparative dissolution profiles of the claimed capsule and the capsule of Hatano.

h) Applicant's arguments regarding Hay are not persuasive because Hay was relied upon for teaching that the polyethylene glycol or polyethylene oxide or polyvinylpyrrolidone-vinylacetate copolymers are known binders.

i) Applicant argues that the stearyl alcohol is washed off after dusting the capsules in Grief, but column 2, lines 62-64 of the Grief reference shows that the dusted capsule is packaged, also stearyl alcohol dusted capsules are spread on trays to dry (see column 4, lines 21, 22). While, Example 1 is a soft capsule, Grief contemplates filling hard and soft gelatin capsules (see column 1, lines 47 and 48). The stearyl alcohol in Grief is part of the capsule and thus can be used in the capsule of Hatano.

j) The statement on page 7 of the office action is meant to convey that that mixture of polyethylene oxide and polyvinylpyrrolidone-vinylacetate copolymers and stearyl alcohol meets the lubricant and excipients of claims 4 and 7-13 ... and 126 and it is further noted that Hatano teaches the presence of hydroxypropylmethylcellulose, which is one of the excipients in claims 7 and 8.

Continuation of 13. Other: a) applicant's belief that the final rejection of 3/17/09 is improper because the examiner introduced two secondary references that have never been cited previously is not persuasive in view of the following: i) applicant filed RCE on 10/30/07, ii) the claims were restricted on 04/15/08, iii) applicant responded to the election/restriction requirement, iv) a non-final rejection rejecting the claims under 35 USC 103 over Hatano in view of Hay, Jr. and Grief was mailed 09/05/08, v) on 12/05/08, applicant responded to the non-final action of 9/5/08, vi) a final rejection was mailed on 3/17/08 in which the rejections of the claims under 35 USC 103 over Hatano in view of Hay, Jr. and Grief were maintained, vii) no new reference was used to reject the claims, viii) therefore, the final rejection mailed 3/17/09 was proper, ix) applicant had the opportunity to address the rejections of 09/05/08, x) the examiner cannot find new references that were applied against the claims in the office action of 3/17/09 .

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,438	01/06/2004	Stephen Mark McAllister	P51223	8426

20462 7590 11/19/2009

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
11/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

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Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10470438	1/6/2004	MCALLISTER ET AL.	P51223

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
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EXAMINER
JAMES W. ROGERS

ART UNIT	PAPER
1618	20091113

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

10The reply filed on 08/07/2009 is not fully responsive to the prior Office action because of the following omission(s) or matter(s): Applicants have not provided a description specific enough to lead the examiner to where support for their new claim amendments might be found. It is noted by the examiner that applicants only state broadly that the amendments are supported in the specification and claims as originally filed. However there are numerous amendments to the claims and new claims 106-109 with 107-109 being in independent form which are newly presented, therefore it is deemed necessary to have a more descriptive account by applicants on where support for these amendments can be found. See 37 CFR 1.111. Since the above-mentioned reply appears to be bona fide, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,438	01/06/2004	Stephen Mark McAllister	P51223	8426

20462 7590 02/09/2009

SMITHKLINE BEECHAM CORPORATION
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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
02/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/470,438	MCALLISTER ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42,44-47,49-54 and 56-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,44-47,49-54 and 56-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/24/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42,44-47,49-54 and 56-105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the examiner could not find the claimed ratio for the copolymer of "7:3:1", present in all independent claims within the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular it is not clear how a pharmaceutical dosage form can be pH independent yet still be soluble, dispersible or disentegratable within a patients acidic gastric environment and neutral to basic intestinal environment. It would seem that in order to be dissolved or dispersed in an acidic environment such as the stomach the formulation would have to be affected by the pH within the gastric environment, the same is also true for the basic environment of the intestine.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 42, 44-47, 49-54, 56-57,59-80, 83, 85-91, 95-99,102 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit *et al.* (U.S. Patent Application Publication No. 2002/0160042) in view of Adams *et al.* (U.S. Patent No. 6,139,875), for the reasons set forth in the office action filed 06/14/2007.

Claims 42,44-47,49-54 and 56-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit *et al.* (U.S. Patent No. U.S. Patent Application Publication No. 2002/0160042) in view of Adams *et al.* (U.S. Patent No. 6,139,875) and Hatano *et al.* (U.S. Patent No. 6,309,666), for the reasons set forth in the office action filed 06/14/2007.

Applicant's arguments filed 11/12/2008have been fully considered but they are not persuasive.

Applicants assert that none of the references cited above teach a pharmaceutical composition which is substantially pH independent since they all relate to enteric coatings which are said to be soluble in the small intestine but are not soluble in low pH gastric environment.

The relevance of this assertion is unclear. Since the composition taught by the combination of references is within the same claimed scope of applicants claimed invention it is inherent that the same composition will have the same properties including its dissolution profile within a patient's body. Applicants have not amended their claims in such a way that the composition is materially different than the composition disclosed by the combination of references above.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,849	01/30/2002	Stephen Mark McAllister	P51223	9605

7590 12/28/2009

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/060,849	MCALLISTER ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The 112 rejections of record have been withdrawn in view of applicant's Remarks filed 09/04/09, at pages 23-27.

Claim Rejections - 35 USC § 103

Claims 1, 2, 7-16, 20-22, 39, 40, 73, 74, 81-74, 87-90, 92-95, 112 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189.

Petereit teaches an injection molding composition comprising: a) 45-100% methacrylate copolymer; b) 0.1-3% lubricant; c) 0-50% drier; d) 0-30% plasticizer; e) 0-100% additives or auxiliaries; f) active agent; and g) 0-20% of another polymer or copolymer (paragraphs 0019-0027). Methacrylate copolymer includes 50-70% methyl acrylate, 10-30% methyl methacrylate, and 5-15% methacrylic acid (a 7:3:1 ratio if converted) (paragraph 0038). Plasticizer includes castor oil, sorbitan ester, and polyethylene glycol (paragraphs 0050-0051). Other polymer or copolymer includes polyvinyl pyrrolidone (paragraphs 0078-0080). Petereit further teaches the shape of the molding includes capsule, part of a capsule such as half or a capsule (paragraph 0095). Petereit also teaches the wall thickness of the obtained capsule is of 0.6 mm (paragraph 0101).

Petereit does not explicitly teach the claimed percent amount of lubricant from 5% to about 30%. However, differences in concentration will not support the

patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select a lubricant amount that falls within the claimed range with the expectation of lat least similar result. This is because Petereit teaches the use of the same lubricant, such as stearyl alcohol, for the same purpose, namely, as a mold releasing agent (paragraphs 0041-0044). Further, the use of lubricant as a mold releasing agent in the claimed amount is known in the art. See for example the teaching of Lehmann at column 3, lines 65-67; and example 1. Lehmann teaches the use of 6% of the mold releasing agent, based on the weight of the polymer. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the molding composition of Petereit using lubricant in the claimed amount in view of the teachings of Lehmann.

Petereit further does not teach that the capsule shell composition is substantially pH-independent. It is noted that nowhere in Petereit does the teaching of pH-dependent disclose. Accordingly, the burden is shifted to applicant to show that the capsule composition of Petereit is substantially pH-dependent. This is because Petereit teaches the use of the same polymers and in the same amounts to prepare a composition for the same purpose desired by the applicant, namely, a capsule shell composition useful in pharmaceutical art.

Claims 3-6, 18 and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Bolles US 3,779,942 and Zentner US 4,795,644.

Petereit is relied upon for the reason stated above. Petereit does not expressly teach the use of surfactant.

Bolles teaches a capsule shell composition comprising well known polymer such hydroxypropyl cellulose, and surfactant such as sodium dioctyl sulfosuccinate in an amount of from about 0.001-10% (abstract; and column 2, lines 20-59). Thus, it would have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include surfactant to obtain the claimed invention. This is because Bolles teaches that the addition of surfactant to improve capsule shell storage stability, uniformity and strength (abstract; and column 2, lines 2-8).

Bolles does not teach the claimed surfactant such as sodium dodecyl sulfate. Zentner teaches useful surfactant for wall forming composition includes sodium dodecyl sulfate, and sodium dioctyl sulfosuccinate (column 13, lines 53 through column 14, lines 1-22). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select sodium dodecyl sulfate as a surfactant, because Zentner teaches the equivalency between sodium dodecyl sulfate, and sodium dioctyl sulfosuccinate, and because Zentner teaches the use of sodium dodecyl sulfate in wall forming composition is known in the art.

Claims 1-33, 35, 38-40, 71-97, 112-132 and 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189, Hatano et al. US 6,309,666, and Klug et al. US 3,314,809.

Petereit is relied upon for the reasons stated above. Petereit further does not teach the inclusion of additives such as lactose and mannitol.

Hatano teaches coated capsule compositions comprising a hard outer shell (abstract). The compositions may be formulated for quick release at a desired location in the gastrointestinal tract (column 2, lines 49-62). Suitable materials for the outer shell include methacrylate co-polymers and acrylic co-polymers (column 5, line 42 to column 6, line 23). Each of the components of the capsule, including the hard outer shell, may include various excipients, including binders, disintegrants, lubricants, aggregation-preventing agents, plasticizer, and a surfactant. Excipients include mannitol, lactose and starch. Binders include ethylcellulose, polyvinylpyrrolidone, HPMC, and polyethylene glycol (column 12, lines 1-11). Disintegrants include polyvinylpyrrolidone and hydroxypropylcellulose (column 12, lines 12-17). Lubricants and aggregation-preventing agents include talc, magnesium stearate, and colloidal silicon dioxide. Plasticizers include diethyl phthalate, dibutyl phthalate, and polyethylene glycol. Surfactants include polyoxyethylene sorbitan monooleate, poiyoxyethylene hydrogenated castor oil, and sodium dodecyl sulfate (column 11, line 52 to column 12, line 65). Such additives may be added in any amount within the scope of the knowledge of one of ordinary skill in the art (column 13, lines 3-5). Thus, it would

have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include the excipients in view of the teachings of Hatano. This is because Hatano teaches the use of well known excipients in pharmaceutical art in capsule shell composition, and because Petereit teaches the desirability of using excipients or other auxiliaries known in the art.

It is noted that applicant argues that Petereit teaches the use of HPC in a long list, and there is no motivation to select HPC. However, Klug teaches a capsule shell composition comprising HPC (columns 1-2). Thus, the skilled artisan would have been motivated to select HPC as other polymer for the capsule shell composition of Petereit in view of the teachings of Klug, because Klug teaches that HPC is the stable thermoplastic material for making excellent articles such as capsule shell (column 4, lines 56 through column 5, lines 1-15).

Response to Arguments

Applicant's arguments filed 09/04/09 have been fully considered but they are not persuasive.

Applicant argues that the formulation of the copolymer blend used in the Petereit process does not teach a combination of two (2) dissolution modifying agents as required by claim 1 herein. One of the dissolution modifying excipients for use in the instant invention is a swellable solid. In Petereit, there is no express statement of swellable solids, but use of a second copolymer. The copolymer is an optional excipient in Petereit's blend, being present from 0-20% w/w. Consequently, the resulting blend

does NOT require such an excipient to being present. The list of polymers suitable for use in the Petereit formulation in disclosed in paragraph 0080 shown below. This paragraph provides for a long list of many polymers not claimed or disclosed for use within the context of Applicants invention as a dissolution modifying excipient. Therefore, even if a copolymer is present one would not necessarily be directed to pick and choose as an excipient that one which Applicant describes as a dissolution modifying excipient.

However, in response to applicant's argument that "*[o]ne of the dissolution modifying excipients for use in the instant invention is a swellable solid. In Petereit, there is no express statement of swellable solids, but use of a second copolymer*", it is noted that the "swellable solid" is recited in a Markush group. Thus, at least independent claim 1 does not necessarily require that the "swellable solid" as one of the dissolution modifying excipient in view of the Markush language. Further, in response to applicant's argument that "*the copolymer is an optional excipient in Petereit's blend, being present from 0-20% w/w. Consequently, the resulting blend does NOT require such an excipient to being present*", the Examiner notes that although the excipient is not required, it can be present. The phrase "optional" clearly indicates that it could be present. Moreover the amount of up to 20% indicates that the excipient does present in the blend.

Moreover, in response to applicant's argument that "*the list of polymers suitable for use in the Petereit formulation in disclosed in paragraph 0080 shown below. This paragraph provides for a long list of many polymers not claimed or disclosed for use*

within the context of Applicants invention as a dissolution modifying excipient", it is noted that the list of dissolution modifying excipients recited in claim 1 is broad. See for example "swellable solid" or "water soluble filler".

Applicant argues that in the present invention:

1) the capsule shell and/or linker is meant to break apart at a particular time, and release the contents of the shell/linker to the GI tract at that time, all at once, not over a period of time to provide a controlled constant rate of release;

2) the 4135F polymeric formulations provide for a capsule shell that has a more delayed, or prolonged time period to release the capsule contents into the GI tract; than a gelatin capsule which is of the immediate release;

3) when a multicomponent dosage form of the present invention, is assembled it is possible to have a shell subunit that disperses the contents as an immediate release, and be linked to a second, or third, etc. shell subunit that disperses the contents as pulsitile releases, much later down the GI tract; and

4) prior to the disclosure by Applicants it was not believed possible to prepare a pH-independent **capsule shell or linker itself** using the copolymers as recited in the presently amended claims.

However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the captured features (1) to (4) above) are not recited at least in the rejected independent claim(s). Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

To place the application in condition for allowance, it is suggested to: 1) clarify the dissolution modifying excipients to include specific combination; and 2) incorporate the above captured features 1-4 into all independent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615

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NOTICE OF ALLOWANCE AND FEE(S) DUE

20462 7590 03/24/2010

GlaxoSmithKline
GLOBAL PATENTS -US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 03/24/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,439	01/20/2004	Stephen Mark MacAllister	P51319	8632

TITLE OF INVENTION: PHARMACEUTICAL FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	06/24/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
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or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20462 7590 03/24/2010

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KING OF PRUSSIA, PA 19406-0939

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,439	01/20/2004	Stephen Mark MacAllister	P51319	8632

TITLE OF INVENTION: PHARMACEUTICAL FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	06/24/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
ROGERS, JAMES WILLIAM	1618	424-451000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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20462 7590 03/24/2010

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P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 03/24/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/470,439	MACALLISTER ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Applicant Arguments/Remarks Made in an Amendment filed 12/11/2009*.

2. ☒ The allowed claim(s) is/are *47,48,50-61,129,130 and 132-137*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 09/09/2009
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dara Dinner on 3/11/2010.

The application has been amended as follows: claims 49,69-76,78-83,85,87-88,90-104,106,108-110,127-128,131 and 138-140 have been canceled.

Claim 47 has been amended as follows:

47. (currently amended) A process for making a pharmaceutical dosage form comprising the steps of:

a) introducing Aminoalkyl Methacrylate Copolymer E present in an amount of about 50 to 90% w/w and an excipient composition comprising at least one dissolution-modifying excipient which is polyethylene oxide present in an amount of about 5 to about 30% w/w; and optionally a second dissolution modifying excipient selected from the group consisting of

i) a swellable solid present in an amount from about 5% to about 60% w/w;

ii) a disintegrant present in an amount of about 5 to 50 % w/w;

iii) a non-reducing sugar present in an amount of about 2.5 to 15% w/w;

iv) a water soluble filler present in the amount of about 5 to 20% w/w;

v) a wicking agent present in the amount of about 2.5% to about 70% w/w;

vi) an inorganic salt present in an amount of 5 to 10% w/w; or a combination or mixture thereof;

and a lubricant present in an amount from 10 to about 25% w/w and optionally a plasticizer from about 0 to 5% w/w and/or a processing agent from about 0 to about 10% w/w; and/or a surfactant present in an amount of about 0.25 to 5% w/w; simultaneously into a first location of an elongated hot melt extruder, the first location having a temperature of about 50°C;

b) mixing said Aminoalkyl Methacrylate Copolymer E and said excipient composition in the hot melt extruder at a temperature ranging from about 50°C to about 125°C to form a homogeneous composition therein and substantially without thermal degradation of the Aminoalkyl Methacrylate Copolymer E and the excipient composition;

(c) extruding the homogeneous composition in the form of a strand from the hot melt extruder though a die at a second location distal from said first location, said second location having a temperature not greater than about 125°C;

c) cutting the strand into pellets; and

d) introducing said pellets into an injection molder and forming a thin-walled capsule shell compartments from said pellets by injection molding, and wherein the shell between and including the inner and outer surfaces of said shell is composed of the extruded and injection molded capsule shell composition.

In claim 48 line 3, the recitation of "croscarmellose sodium," has been deleted.

In Claim 133 line 2, the recitation of "10 to 20" has been deleted and replaced with "5 to 30".

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/895,588	07/21/2004	Stephen Mark McAllister	PU60404	7883

7590 07/08/2010

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
07/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/895,588	MCALLISTER ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35-46,48-51,53,54,56,57 and 76-94* is/are pending in the application.

4a) Of the above claim(s) *6,13,26,27,30,31,33,36,76-80,83 and 85-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12,14-25,28,29,32,35,37-46,48-51,53,54,56-61,64-75,81,82,84, and 89-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants': amendment to the claims, amendment to the specification, and remarks, filed on 27 February 2010.
- The 35 USC 112, second paragraph rejection is withdrawn in view of the amendment.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-12, 14-25, 28, 29, 32, 35, 37-46, 48-51, 53, 54, 56-61, 64-75, 81, 82, 84, and 89-94 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0160042 ("Petereit"), in view of U.S. Patent No. 6,270,797 ("Gidwani"), further in view of U.S. Patent No. 6,139,875 ("Adams"), further in view of U.S. Patent No. 3,779,942 ("Bolles"), further in view of U.S. Patent No. 4,795,644 ("Zentner"), further in view of U.S. Patent No. 4,564,363 ("Bagnall") further in view of U.S. Patent No. 6,387,401 ("Rosenberg").

Petereit reference teaches injection-molded capsules, which may comprise methacrylate copolymers composed of from 50% to 70% by weight of methyl acrylate, 10 to 30% by weight of methyl methacrylate, and 5% to 15% by weight of methacrylic acid (see abstract and p. [0038]). The ratio of free carbosyl groups to ester groups of

1:10 is inherent to the disclosed polymers. The capsule may include other components, such as a release agent, a plasticizer, additives or auxiliaries, pharmaceutical agents, and other polymers or copolymers (see abstract). Plasticizers such as triethyl citrate and tributyl citrate may be included in amounts ranging up to about 30% by weight (see p. [0049] to [0051]). Polymers such as hydroxypropyl cellulose and polyvinylpyrrolidones may be included in amounts of up to 20% by weight (see p. [0078] to [0080]). The processing of the ingredients takes place in an extruder in a temperature ranging from 120°C to 250°C (see p. [0030]). In one embodiment, the mixture is processed in a twin-screw extruder, with the resulting extrudate bring chopped to give pellets (see [0099]). The molded capsules may be joined by various methods including adhesive bonding, welding by laser, ultrasound or microwaves, or by means of a snap connection (see p. [0095]). In one embodiment, a capsule with a wall thickness of 0.6 mm is produced (see p. [0101]).

Petereit differs from the instant application in that it does not explicitly teach at least two hydroxypropyl cellulose polymers having a differing molecular weight.

Gidwani teaches a matrix system for sustained release of an active agent (see col. 3, lines 51-53). The system comprises use of mixtures of ydrophilic polymers such as hydroxypropyl cellulose (KLUCEL) (see col. 3, lines 53-61, example 4). The molecular weight of hydroxypropyl cellulose is disclosed at a range of 80,000 to 115,000 (see col. 4, lines 1-3). A combination of the different molecular weights of the same polymer and/or different molecular weights of the same polymer and/or different polymers may be employed (see col. 4, lines 3-5). Gidwani explains that use of

hydrophilic polymers in sustained release systems is important to achieve approximately zero-order release over a prolonged period of time by achieving proper erosion of the matrix and dissolution (see col. 3, lines 14-27).

The Petereit reference does not teach the inclusion of lubricants or processing agents in the concentrations being claimed instantly.

Adams teaches an enteric composition comprising an enteric polymer, about 5 to 45 weight percent of a hydrophobic compound such as stearyl alcohol, and about 5 to 50 weight percent of a water-insoluble flake material such as talc (see col. 8, examples 1-8; and claims 1-5). Such additives allow for the enteric composition to achieve superior material and release properties (see col. 2, lines 41-65).

The Petereit reference differs from the instant application in that it does not teach a surfactant in the concentrations being claimed instantly.

Bolles teaches a capsule shell composition (see col. 1, lines 34-45). The disclosed composition comprises, *inter alia*, surfactants at a concentration of 0.001-10% (see col. 2, lines 17-21). Bolles explains that inclusion of surfactant in the shell composition considerably increases the shelf, storage, or half-life of the capsules (see col. 2, lines 2-6). Disclosed surfactants include hydrocarbon surfactans such as sodium dioctyl sulfosuccinate sodium carboxymethyl cellulose, and polyoxyethylene polyol fatty acid esters (see col. 2, lines 53-57). Bolles does not disclose sodium dodecyl sulfate as a surfactant, however use of sodium dodecyl sulfate in oral dosage forms was known in the art at the time the instant application was filed, as evinced by Zentner (see col. 14, line 13).

The Petereit reference differs from the instant application in that it does not a dissolution modifying disintegrant in the concentrations being claimed.

Bagnall teaches a capsule-like container comprising an outer-wall comprised of a biodegradable polymeric material (see col. 2, lines 30-35). Disintegrants such as sodium starch glycolate are also disclosed (see col. 2, line 66) at a concentration of 2-10% (see col. 3, line 1).

The Petereit reference differs from the instant application in that it does not disclose an absorption enhancer. However, use of absorption enhancers, such as lechithin, in extruded pharmaceutical compositions was known in the art at the time the instant application was filed, as shown by Rosenberg (see claims 1 and 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a capsule composition comprising a copolymer of methyl acrylate, methyl methacrylate and methacrylic acid, at least two hydroxypropyl cellulose polymers, a lubricant, a dissolution modifying excipient, a surfactant, a plasticizer, a processing agent, and an absorption enhancer, as taught by Petereit, in view of Gidwani, further in view of Adams, further in view of Bolles, further in view of Zenter, further in view of Bagnall, further in view of Rosenberg. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in an injection molded composition with high mechanical strength and high heat resistance, as explained by Petereit. Addition of hydroxypropyl cellulose polymers is important to achieve approximately zero-order release over a prolonged period of time by achieving proper erosion of the matrix and dissolution, as

explained by Gidwani. Addition of a lubricant such as steryl alcohol and a processing agent such as talc allow for the enteric composition to achieve superior material and release properties, as explained by Adams. Addition of surfactant in the shell composition considerably increases the shelf, storage, or half-life of the capsules, as explained by Bolles. See above.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-12, 14-25, 28, 29, 32, 35, 37-46, 48-51, 53, 54, 56-61, 64-75, 81, 82, 84, and 89-94 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application Nos. 10/060,603; 10/060,849; 10/470,439; 10/565,462; 11/078,077; and 10/519,158.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the each of the

above-cited copending applications claim similar subject matter. For example, Application No. 10/060,603 ("'603") claims a capsule comprising a shell being composed of an extruded and injection molded capsule shell composition comprising aminoalkyl methacrylate copolymer E (30-90%), a lubricant (0-30%), at least one dissolution modifying excipient (5-70%), a plasticizer (0-5%), and a processing agent (0-10%) (*see* claim 1). '603 does not claim at least two hydroxypropyl cellulose polymers, however Gidwani teaches a matrix system for sustained release of an active agent comprising use of mixtures of ydrophilic polymers such as hydroxypropyl cellulose (KLUCEL). The molecular weight of hydroxypropyl cellulose is disclosed at a range of 80,000 to 115,000 (see above). Thus, the compositions recited in the claims of the copending applications listed above are directly within the scope of the compositions of the instant claims.

This is a genus-species situation, wherein the numerous species of the copending application claims are directly within the scope of the large genus of the pending claims, thereby creating an 'anticipation situation' in obvious type double patenting.

There are numerous applications that may necessitate a double patenting rejection due to the breadth of the claims, as can be seen by an inventors name search of US Patents and Applications. It would constitute an undue burden for the Examiner to specifically analyze each of the numerous patent applications. A quick search turned up the copending applications above that appear to have similar subject matter as claimed. The Examiner requests a complete list of both patents and pending

applications, which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicants' arguments filed on 27 February 2010 have been fully considered but they are not persuasive.

Applicants argue that Petereit does not teach a combination of a blend of two hydroxypropyl cellulose polymers, each having different molecular weights. See remarks, pages 31-33.

Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Gidwani was cited for this teaching (see substantive rejection, above).

Applicants argue that a second copolymer is an optional excipient in Petereit. See remarks, page 31.

The applicants' arguments are based on what the examiner believes to be a narrow interpretation of the prior art. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843

(Fed. Cir.), *cert. Denied*, 493 U.S. 975 (1989). It is the position of the examiner that one of ordinary skill in the art, given both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

Applicants argue that even if a copolymer is present one would not necessarily be directed to pick and choose as an excipient that one which Applicant describes as two HPC's of different molecular weight. See remarks, paragraph bridging pages 31 and 32.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). MPEP 2144.06.

Additionally, as indicated above, Gidwani was cited for this teaching.

Applicants argue that Gidwani is non-analogous art. See remarks, page 34.

Examiner respectfully submits that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Gidwani and Petereit share the same field of endeavor.

Applicants argue that Adams teaches amounts of talc that exceed that of applicants' claim 1. See remarks, page 36.

Adams teaches 5-50% talc (see claims 1-5). Instant claim 1 recites lubricant amount of 10-25%. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Applicants argue that Petereit specifically reduced the amount of mold release agent needed in the formulation. See remarks, page 36.

Examiner respectfully submits that the reduced amount taught my Petereit may be within the 10-25% claimed instantly. In any event, Adams teaches a lubricant concentration which overlaps with that claimed instantly (see above).

Applicants argue that Adams does not use the word "release" in the same way as the instant application. See remarks, page 37.

It is the position of the examiner that one of ordinary skill in the art, given both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. *See* MPEP § 2111 and 2123.

Applicants argue that the temperature and pressures needed to extrude and injection mold the shells and linker subunits herein is not the same as that of the encapsulation process of the '942 patent. See remarks, page 38.

The processes of extrusion and injection molding are not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicants argue that the '942 patent does not produce a "subunit". See remarks, page 39.

The plurality of subunits is deemed to be a matter of engineering design choice, and thus does not serve to patentably distinguish the claimed subject matter over the prior art. *In re Kuhle*, 526 F. 2d. 553, 188 USPQ 7 (CCPA 1975).

Applicants argue that the goal of Zenter is to deliver to the GI tract a drug at a substantially constant rate. See remarks, page 40.

The difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. Denied, 500 U.S. 904 (1991) ... ."

Applicants argue that there is no teaching, suggestion, or motivation to combine Petereit with Gidwani, Adams, Bolles, or Zentner. See remarks, page 41.

Examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). As indicated above, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been

individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). MPEP 2144.06.

Regarding the provisional obviousness-type double patenting rejections, applicants argue that the rejection is unclear as to why the claims are not patentably distinct. See remarks, page 45.

As indicated in the rejection, this is a genus-species situation, wherein the numerous species of the copending application claims are directly within the scope of the large genus of the pending claims, thereby creating an 'anticipation situation' in obvious type double patenting.

There are numerous applications that may necessitate a double patenting rejection due to the breadth of the claims, as can be seen by an inventors name search of US Patents and Applications. It would constitute an undue burden for the Examiner to specifically analyze each of the numerous patent applications. A quick search turned up the copending applications above that appear to have similar subject matter as

claimed. The Examiner requests a complete list of both patents and pending applications, which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,462	01/20/2006	Stephen Mark McAllister	PU60404	9920

20462 7590 07/19/2010

GlaxoSmithKline
GLOBAL PATENTS -US, UW2220
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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
07/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,462	MCALLISTER ET AL.	
	Examiner	Art Unit	
	S. TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2010*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-41 and 44-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *37-41 and 44-106* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 37-41 and 44-70 are drawn to a multi-component dosage form, classified in class 424, subclass 489.

II. Claims 71-106 are drawn to a capsule dosage form, classified in class 424, subclass 451.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related product. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, and function. See for example, the product of Group I does not require the outer and the opposed inner surface of Group II. Similarly, the product of Group II does not require that the drug substance-containing capsule compartment is soluble or disintegrable in a patient's gastro-intestinal environment.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species:

1) solid matrix comprising at least two hydroxypropyl cellulose polymer, please select a single species from claims 38-40 and from Markush Group in claims 66 or 74-77;

2) lubricant: please select from Markush Group recited in claim 41;

3) at least one dissolution modifying excipient, please select a single species from: a) disintegrant, b) swellable solid, c) non-reducing sugar, d) water soluble filler, 3) wicking agent, or f) an inorganic salt;

4) if disintegrant is selected, please select a single species from Markush Group of claim 46 or 81;

5) if swellable solid is selected, please select a single species from claim 50 or 85;

6) plasticizer: please select a single species from claim 53 or 88;

7) absorption enhancer: please select a single species from claim 56 or 91;

8) surfactant: a) sodium dodecyl sulphate, or b) block copolymer of ethylene oxide and propylene oxide;

9) second dissolution modifying excipient: a) wicking agent, b) sodium starch glycollate, or c) croscarmellose sodium;

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 37 and 71 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

No telephone communication was made because the requirement for restriction is complex.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/078,077	03/11/2005	Adrian Brown	PU60746	8251

7590 03/31/2010

GLAXOSMITHKLINE
Corporate Intellectual Property- UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
03/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/078,077	BROWN ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
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Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-12,14-27,29-40 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-12,14-27,29-40 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

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1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response, Amendment and Applicant's Arguments/Remarks after Non-Final Office Action, all filed 08/03/09 and 12/18/09 is acknowledged.

Applicant has overcome the following objection(s) and/or rejection(s) by virtue of the amendment to the claims and/or persuasive remarks: (1) The claim objections for claims 17 and 40 have been withdrawn; (2) The 35 U.S.C. §112, second paragraph rejection of claims 14, 17, 30, 32 and 36 have been withdrawn; (3) The 35 U.S.C. §102(e) rejections of claims 1-43 over McAllister (U.S. Pat. Pubn. No. 2003/0068369); McAllister (U.S. Pat. Pubn. No. 2003/0049311) and Clarke (U.S. Pat. No. 7,163,693) have been withdrawn; (4) The U.S.C. §103(a) rejection of claims 1-43 over Berndl (U.S. Pat. Pubn. No. 2004/0013697) has been withdrawn.

Claims 1-7, 9-12, 14-27, 29-40 and 48 are pending in this action. Claims 1-4, 9, 11, 14-21, 27, 29, 30, 32, 34-37 and 40 have been amended. New claim 48 has been added. Claims 8, 13, 28 and 41-47 have been cancelled. Claims 1-7, 9-12, 14-27, 29-40 and 48 remain rejected.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "*the dosage form of claim 2, wherein the lubricant is stearyl alcohol...*" in lines 1-2, respectively. There is insufficient antecedent basis for this limitation in the claim. (Claim 2 from which claim 12 depends does not reference any "lubricant").

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9-12, 14-27, 29-40 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAllister *et al.* (hereinafter "McAllister") (U.S. Pat. Appln. Pubn. No. 2003/0068369).

McAllister ('369) teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form (see Abstract). Also disclosed are injection-molded capsule shells, linkers, spacers, multi-component injection molded capsule shells, linkers, spacers and multicomponent dosage forms (page 1, ¶ 0007 & 0012). These limitations read on a "capsule having a shell…the shell being composed of an extruded and injection molded composition".

Polymers suitable for injection molding include PEO, PEG, mixtures of PEO & PEG, PVA, PVP, cellulose derivatives such as hydroxypropyl cellulose, hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, starch and its derivatives, sodium starch glycolate, polysaccharides such as chitosan, polyacrylates and poly(meth)acrylates and its derivatives such as the Eudragit® family of polymers and combinations and mixtures thereof (p. 9, ¶ 0122).

More suitable methacrylic acid copolymers disclosed include Eudragit®RL and/or Eudragit®RS (p. 10, ¶ 0125). The copolymers can be used in amounts of 20% w/w or more (p.

10, ¶ 0127). Preferred polymers disclosed are Eudragit®RL 100. A suggested blend of polymers would be the combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0131).

Water soluble and water-insoluble polymers are discussed at p. 10, ¶ 0136-0137).

The polymer material includes substances which modify their properties, such as: lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like (p. 11, ¶ 0142). Specific substances are disclosed at page 11, (p. 11, ¶ 0143 - p. 12 ¶ 0156). These substances (lubricant - i.e., stearyl alcohol; surfactant; plasticizers, etc.) are the same as those claimed by Applicant. Lubricants are disclosed in amounts of from about 0 to about 30% w/w (p. 12, ¶ 0154). Suitable amounts of dissolution modifying agents (i.e., disintegrants) are about 10% to 40% as well as 10% to 70% for swellable solids such as hydroxypropylcellulose (p. 12, ¶ 0152).

With regards to the amounts and/or ranges being claimed, it is the position of the Examiner that suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regards to new claim 48, which recites that the "capsule shell has a wall with a thickness in the range of about 0.1-0.8 mm", McCallister meets this limitation. McCallister

teaches at page 3, paragraph [0024], that the "side wall of the capsule is composed of a plurality of panels, each having a thickness in the range of about 0.2 to 0.3 mm". This capsule shell thickness range reads on and overlaps with Applicant's claimed range. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of McCallister. McCallister explicitly teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms. The prior art teaches formulations as are instantly claimed that comprise the same ingredients, in similar amounts and produced in the same manner (i.e., injection-molding) as that desired and sought by Applicant.

* * * * *

Claims 1-7, 9-12, 14-27, 29-40 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAllister *et al.* (hereinafter "McAllister") (U.S. Pat. Appln. Pubn. No. 2003/0049311).

McAllister ('311) teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form

(see Abstract). Also disclosed are injection-molded capsule shells, linkers, spacers, multi-component injection molded capsule shells, linkers, spacers and multicomponent dosage forms (page 1, ¶ 0007 & 0012).

Polymers suitable for injection molding include PEO, PEG, mixtures of PEO & PEG, PVA, PVP, cellulose derivatives such as hydroxypropyl cellulose, hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, starch and its derivatives, sodium starch glycolate, polysaccharides such as chitosan, polyacrylates and poly(meth)acrylates and its derivatives such as the Eudragit® family of polymers and combinations and mixtures thereof (p. 9, ¶ 0120).

More suitable methacrylic acid copolymers disclosed include Eudragit®RL and/or Eudragit®RS (p. 10, ¶ 0123). The copolymers can be used in amounts of 20% w/w or more (p. 10, ¶ 0125). Preferred polymers disclosed are Eudragit®RL 100. A suggested blend of polymers would be the combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0130).

Water soluble and water-insoluble polymers are discussed at p. 10, ¶ 0135-0136). The polymer material includes substances which modify their properties, such as: lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like (p. 11, ¶ 0141). Specific substances are disclosed at page 11, (p. 11, ¶ 0143 – p. 12 ¶ 0160). These substances (lubricant - i.e., stearyl alcohol; surfactant; plasticizers, etc.) are the same as those claimed by Applicant. Lubricants are disclosed in amounts of from about 0 to about 30% w/w (p. 12, ¶ 0155). Suitable amounts of dissolution modifying agents (i.e., disintegrants, swellable solids) are provided in amounts of from about 2.5% to 70% w/w (p. 11, ¶ 0146).

With regards to the amounts and/or ranges being claimed, it is the position of the Examiner that suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regards to new claim 48, which recites that the "capsule shell has a wall with a thickness in the range of about 0.1-0.8 mm", McCallister meets this limitation. McCallister teaches at page 3, paragraph [0024], that the "side wall of the capsule is composed of a plurality of panels, each having a thickness in the range of about 0.2 to 0.3 mm". This capsule shell thickness range reads on and overlaps with Applicant's claimed range. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of McCallister. McCallister explicitly teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms. The prior art teaches formulations as are instantly claimed that comprise the same ingredients, in similar amounts and produced in the same manner (i.e., injection-molding) as that desired and sought by Applicant.

* * * * *

Claims 1-7, 9-12, 14-27, 29-40 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke *et al.* (hereinafter "Clarke") (U.S. Patent No. 7,163,693).

Clarke ('693) teaches a multi-component pharmaceutical dosage form comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form (see Abstract).

Polymers suitable for injection molding include PEO, PEG, mixtures of PEO & PEG, PVA, PVP, cellulose derivatives such as hydroxypropyl cellulose, hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, starch and its derivatives, sodium starch glycolate, polysaccharides such as chitosan, polyacrylates and poly(meth)acrylates and its derivatives such as the Eudragit® family of polymers and combinations and mixtures thereof. Particularly suitable methacrylic acid copolymers disclosed include Eudragit®RL and/or Eudragit®RS (column 10, lines 42-57); (col. 11, lines 3-19).

The polymer material includes substances which modify their properties, such as: lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like (col. 11, lines 20-36).

With regards to the amounts and/or ranges being claimed, it is the position of the Examiner that suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are

variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regards to new claim 48, which recites that the "capsule shell has a wall with a thickness in the range of about 0.1-0.8 mm", Clarke meets this limitation. Clarke teaches at column 8, lines 15-23 that the "wall of the capsule compartment is preferably 0.1-0.8 mm thick". This capsule shell thickness range of Clark reads on and exactly overlaps with Applicant's claimed range. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Clarke.

* * * * *

Pertinent Art:

Prior art, made of record, cited of interest and deemed relevant by Examiner:

U.S. Patent Nos: 6,284,803; 6,318,650; 6,517,866; 6,797,283.

* * * * *

Response to Arguments

Applicant's arguments filed 08/03/09 have been fully considered and were found to be partially persuasive.

- **Claim Objections:**

Applicant argued, "While Applicants disagree with the Examiner, claims 17 and 40 have been amended accordingly."

This was found persuasive, based on the amendment to the claims. Accordingly, the claim objections for claims 17 and 40 have been withdrawn.

- **Claim Rejections - 35 USC § 112:**

Applicant argued, "Claim 14 has been amended to remove the terminology of or other hydroxyalkylcellulose derivative".

Applicant argued, "For claims 17, 30 and 32, claim 17 has been amended to depend upon claim 16; claim 28 has been added to claim 27 and the claim dependencies of claims 30 and 32 are appropriately corrected."

Applicant argued, "Claim 36 has been amended to remove the abbreviation of HPC".

These arguments were found persuasive, based on the amendment to the claims. Accordingly, the 35 U.S.C. §112, second paragraph rejection of claims 14, 17, 30, 32 and 36 have been withdrawn.

- **Claim Rejections - 35 USC § 102(e) over McCallister ('369):**

Applicant argued, "In contrast to the instant application, the claims and the specification of the '369 case are directed to the use of the polymer Eudragit 4135F, not the polymers Eudragit RL or RS100 as claimed herein, which are generally referred to as Aminoalkyl Methacrylate

Copolymers. A key functionality of both of these polymers is that they are pH independent. In contrast, the 4135F polymer is pH dependent at pH>7.0. The '369 publication does not disclose the inclusion of Eudragit RL100 or RS100 present in an amount of about 10 to about 80%."

Applicant's arguments have been considered and were found persuasive. Accordingly, the 35 U.S.C. §102(e) rejection of claims 1-43 over McAllister ('369) has been withdrawn.

However, this rejection has now been reformulated as a 35 U.S.C. §103(a) rejection. The McCallister '369 reference is suggestive of the teaching of the use of the polymers - Eudragit®RL and/or Eudragit®RS as claimed (p. 10, ¶ 0125). The reference is also suggestive of blends of polymers comprising a combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0131). While the reference prefers to utilize Eudragit 4135F, the Examiner points out that Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). In addition, whilst McCallister does not explicitly teach the claimed amounts and/or ranges, it remains the position of the Examiner suitable amounts and/or ranges could be determined by one of ordinary skill in the art through routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

- **Claim Rejections - 35 USC § 102(e) over McCallister ('311):**

Applicant argued, "The '311 publication is directedto the use of the copolymer Eudragit E100 and does not disclose the inclusion of Eudragit RL100 or RS100 present in an amount of about 10 to about 80%."

Applicant's arguments have been considered and were found persuasive. Accordingly, the 35 U.S.C. §102(e) rejection of claims 1-43 over McAllister ('311) has been withdrawn.

However, this rejection has now been reformulated as a 35 U.S.C. §103(a) rejection. The McCallister '311 reference is suggestive of the teaching of the use of the polymers - Eudragit®RL and/or Eudragit®RS as claimed (p. 10, ¶ 0123). The reference is also suggestive of blends of polymers comprising a combination of RL and RS with the necessary glidants and excipients (p. 10, ¶ 0130). With respect to the claimed amounts and/or ranges, as delineated above, the determination of suitable or effective amounts is within the level of the skilled artisan. See *In re Aller*. Applicant argues that "McCallister (in paragraph 0123) does not teach how one formulates such a polymer to injection mold it, nor what specific excipients and amounts are necessary. This argument was not deemed convincing. Note in particular that McCallister explicitly teaches pharmaceutical polymeric compositions suitable for injection molding of single or multi-component pharmaceutical dosage forms comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the

assembled dosage form by a weld between parts of the assembled dosage form (see Abstract). The reference also teaches injection-molded capsule shells, linkers, spacers, multi-component injection molded capsule shells, linkers, spacers and multicomponent dosage forms (page 1, ¶ 0007 & 0012). Thus, the reference vividly teaches injection molded formulations (i.e., capsules) as claimed. The reference further teaches use of the same components (lubricant - i.e., stearyl alcohol; surfactant; plasticizers, etc.) as that claimed by Applicant. The reference further discloses suitable amounts of dissolution modifying agents (i.e., disintegrants, swellable solids) provided in amounts of from about 2.5% to 70% w/w (p. 11, ¶ 0146). Hence, the prior art teaches injection molded capsules comprising the formulation excipients as claimed herein by Applicant. Applicant's argument that "Injection molded articles with such polymers is not the novelty of the present invention and that it is the specific formulations that provide for consistent release of the article from the mold and for use in humans as a capsule component" was not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., consistent release of the article from the mold) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this regard, the claims are entirely silent in terms of any reference to release, rates of release or dissolution profiles. Thus, Applicant's arguments are not commensurate in scope with the claims, which do not require "consistent release" as argued herein by Applicant.

- **Claim Rejections - 35 USC § 102(e) over Clarke ('693):**

Applicant argued, "The '693 patent is directed to the underlying multicomponent dosage forms which the '311 and '369 and the instant application all form the compositions of. The '693 patent does not provide the specifics of the claimed invention herein."

Applicant's arguments have been considered and were found persuasive. Accordingly, the 35 U.S.C. §102(e) rejection of claims 1-43 over Clarke ('693) has been withdrawn.

However, this rejection has now been reformulated as a 35 U.S.C. §103(a) rejection. The Clarke reference as noted, above, teaches a multi-component pharmaceutical dosage form comprising a plurality of drug substance containing sub-units, being capsule compartments and/or solid subunits comprising a solid matrix of a polymer which contains a drug substance, the sub-units being connected in the assembled dosage form by a weld between parts of the assembled dosage form (see Abstract). The reference also teaches polymers suitable for injection molding. Particularly suitable methacrylic acid copolymers are disclosed and include Eudragit®RL and/or Eudragit®RS (column 10, lines 42-57); (col. 11, lines 3-19). The further addition of lubricants, surfactants, absorption enhancers, plasticizers, dissolution modifying agents and the like is also discussed (col. 11, lines 20-36). With respect to the claimed amounts and/or ranges, as delineated above, the determination of suitable or effective amounts is within the level of the skilled artisan. See *In re Aller*.

- **Claim Rejections - 35 USC § 103(a) over Berndl ('697):**

Applicant argued, "Berndl is directed to self-emulsifying formulations; the present application is not a self-emulsifying formulation."

Applicant's arguments have been considered and were found persuasive. Accordingly, the U.S.C. §103(a) rejection of claims 1-43 over Berndl (U.S. Pat. Pubn. No. 2004/0013697) has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

- No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

March 26, 2010

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,603	01/30/2002	Stephen Mark McAllister	P51319	8276

7590 06/04/2010

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No.	Applicant(s)	
	10/060,603	MCALLISTER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on *09 April 2010* is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
- ☐ B. New paragraph(s) should not be underlined.
- ☐ C. Other _____.

☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
- ☐ B. Other _____.

☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
- ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
- ☐ C. Other _____.

☐ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
- ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
- ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
- ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
- ☒ E. Other: *See Continuation Sheet*.

☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):
_____

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.

2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

   Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

   Failure to timely respond to this notice will result in:
   Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or
   Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

/Blessing M. Fubara/ Primary Examiner, Art Unit 1618	

Notice of Non-Compliant Amendment (37 CFR 1.121)

Continuation of 4(e) Other: Claim 1 filed 9/17/09 had "selected from" so that the phase is not a new addition to the claim 1 as indicated by the underlining in the current amendment; claim 22 has the status identifier of "withdrawn/amended" but the claim is not currently amended; the status identifier for claims 77-79, 83, 90, 114 and 115 should be ---withdrawn/previously amended--- because these claims were amended on 9/17/09 .

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,603	01/30/2002	Stephen Mark McAllister	P51319	8276

7590 10/06/2009

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/060,603	MCALLISTER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *17 September 2009*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: See *Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-13, 23, 26-28, 108-111, 117-120 and 126*.
   Claim(s) withdrawn from consideration: *14-22,24,25,69-102,105,106,112-116 and 121-125*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 9/9/2009
13. ☒ Other: See Continuation Sheet.

/Blessing M. Fubara/
Examiner, Art Unit 1618

Continuation of 3. NOTE: Amendment to claim 1 indicating that the lubricant is no longer optional, including wicking agent, inorganic salt, lactose, and non-reducing sugar to the composition of claim 1 requires further consideration and search and the amendment are not deemed to place the claims in condition for allowance .

Continuation of 11. does NOT place the application in condition for allowance because: a) applicant's argument that the provisional obviousness type double patenting rejection is improper because the current claims are the subject of restriction requirement in the co-pending application 10/470,439 does not overcome the rejection, i) the provisional rejection is maintained because the claims are not allowable over the prior art and ii) this application was not filed as a divisional application of 10/470,439 and in fact, the application has not claimed priority for 10/470,439.

b) Applicant's arguments that Hatano does not teach the limitations of the claims are not persuasive because Hatano teaches lubricants, binders and EUDRAGIT E 100 coated capsules (see column 6, lines 1-12; column 9, lines 51-65; column 10, line 65 to column 11, line 4; column 12, lines 1-34). While Hatano does not teach the exact percent amounts of these polymers, the artisan in formulating the capsule of Hatano would use appropriate amounts suitable for the capsule formulation. Lubricant, plasticizers and processing agents are optional in claim 1. The rejection was based on combination of references with Hay teaching that the polyethylene glycol or polyethylene oxide or polyvinylpyrrolidone-vinylacetate copolymers are known binders, and Grief teaching hard capsules to comprise of stearyl alcohol lubricant. Hatano teaches the capsule shell to comprise 48% EUDRAGIT E 100 in Example 1 at column 16 and that intersects the amount of the EUDRAGIT in the range of 30-90% recited in claim 1. Therefore, contrary to applicant's suggestion, Hatano teaches EUDRAGIT E 100 in an amount of 48%; Lubricant and plasticizer is optional in claim 1, but the Hay and Grief provide what is missing in Hatano. Applicant is arguing against the Hatano art separately when the rejection was made over combination of references.

c) With regards to the presence of a second excipient in the capsule shell of claim 7, it is noted that Hatano further coats the EUDRAGIT shell with HPMCAS or hydroxypropylmethylcellulose (Examples 1 and 3) with the hydroxypropylmethylcellulose meeting the limitations of claim 7.

d) With regards to claim 108, the artisan in formulating the capsule would use specific amounts that would lead to the desired release and in fact, in Hatano, the hydroxypropylmethylcellulose is at 24%, which is a point within the recited range of 5-60%.

e) injection molding and extrusion and processes of making the coating are processes of making the product and does not patentably distinguish the capsule of the claim from the capsule of the prior art.

f) Applicant's argument that the claimed capsule shell is not the layered capsule of Hatano's claims and that the capsule is coated in Hatano is not persuasive to overcome the rejections and place the claims in condition for allowance because, Hatano is not limited to the claims but the whole document is evaluated for what it teaches and the comprising language of the claims is open and does not exclude layers.

g) The amendment filed after prosecution is closed has not been entered and applicant's argument regarding the amendment after final is therefore moot.

h) Applicant argues that the capsule composition of Hatano is a control and delay release product while the product of the claim is an immediate release dosage form that dissolves within 17-34 "minute window" as shown in Figure 2. The examiner disagrees with the applicant that the claimed capsule is immediate release and the capsule of Hatano is a delayed or sustained release because applicant has not limited the claims to immediate release. Also, applicant's specification contemplates immediate release, sustained release and pulse release units (see paragraphs [0018], [0046] of the published application). Furthermore, Figure 2 of the specification is a demonstration of the dissolution profile of polymeric compositions (see paragraph [0028] of the published application) and not comparative dissolution profiles of the claimed capsule and the capsule of Hatano.

h) Applicant's arguments regarding Hay are not persuasive because Hay was relied upon for teaching that the polyethylene glycol or polyethylene oxide or polyvinylpyrrolidone-vinylacetate copolymers are known binders.

i) Applicant argues that the stearyl alcohol is washed off after dusting the capsules in Grief, but column 2, lines 62-64 of the Grief reference shows that the dusted capsule is packaged, also stearyl alcohol dusted capsules are spread on trays to dry (see column 4, lines 21, 22). While, Example 1 is a soft capsule, Grief contemplates filling hard and soft gelatin capsules (see column 1, lines 47 and 48). The stearyl alcohol in Grief is part of the capsule and thus can be used in the capsule of Hatano.

j) The statement on page 7 of the office action is meant to convey that that mixture of polyethylene oxide and polyvinylpyrrolidone-vinylacetate copolymers and stearyl alcohol meets the lubricant and excipients of claims 4 and 7-13 ... and 126 and it is further noted that Hatano teaches the presence of hydroxypropylmethylcellulose, which is one of the excipients in claims 7 and 8.

Continuation of 13. Other: a) applicant's belief that the final rejection of 3/17/09 is improper because the examiner introduced two secondary references that have never been cited previously is not persuasive in view of the following: i) applicant filed RCE on 10/30/07, ii) the claims were restricted on 04/15/08, iii) applicant responded to the election/restriction requirement, iv) a non-final rejection rejecting the claims under 35 USC 103 over Hatano in view of Hay, Jr. and Grief was mailed 09/05/08, v) on 12/05/08, applicant responded to the non-final action of 9/5/08, vi) a final rejection was mailed on 3/17/08 in which the rejections of the claims under 35 USC 103 over Hatano in view of Hay, Jr. and Grief were maintained, vii) no new reference was used to reject the claims, viii) therefore, the final rejection mailed 3/17/09 was proper, ix) applicant had the opportunity to address the rejections of 09/05/08, x) the examiner cannot find new references that were applied against the claims in the office action of 3/17/09 .

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,438	01/06/2004	Stephen Mark McAllister	P51223	8426

20462 7590 11/19/2009

SMITHKLINE BEECHAM CORPORATION
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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
11/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10470438	1/6/2004	MCALLISTER ET AL.	P51223

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EXAMINER
JAMES W. ROGERS

ART UNIT	PAPER
1618	20091113

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

10The reply filed on 08/07/2009 is not fully responsive to the prior Office action because of the following omission(s) or matter(s): Applicants have not provided a description specific enough to lead the examiner to where support for their new claim amendments might be found. It is noted by the examiner that applicants only state broadly that the amendments are supported in the specification and claims as originally filed. However there are numerous amendments to the claims and new claims 106-109 with 107-109 being in independent form which are newly presented, therefore it is deemed necessary to have a more descriptive account by applicants on where support for these amendments can be found. See 37 CFR 1.111. Since the above-mentioned reply appears to be bona fide, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,438	01/06/2004	Stephen Mark McAllister	P51223	8426

20462 7590 02/09/2009

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
02/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/470,438	MCALLISTER ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42,44-47,49-54 and 56-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,44-47,49-54 and 56-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/24/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42,44-47,49-54 and 56-105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the examiner could not find the claimed ratio for the copolymer of "7:3:1", present in all independent claims within the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular it is not clear how a pharmaceutical dosage form can be pH independent yet still be soluble, dispersible or disentegratable within a patients acidic gastric environment and neutral to basic intestinal environment. It would seem that in order to be dissolved or dispersed in an acidic environment such as the stomach the formulation would have to be affected by the pH within the gastric environment, the same is also true for the basic environment of the intestine.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 42, 44-47, 49-54, 56-57,59-80, 83, 85-91, 95-99,102 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit *et al.* (U.S. Patent Application Publication No. 2002/0160042) in view of Adams *et al.* (U.S. Patent No. 6,139,875), for the reasons set forth in the office action filed 06/14/2007.

Claims 42,44-47,49-54 and 56-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit *et al.* (U.S. Patent No. U.S. Patent Application Publication No. 2002/0160042) in view of Adams *et al.* (U.S. Patent No. 6,139,875) and Hatano *et al.* (U.S. Patent No. 6,309,666), for the reasons set forth in the office action filed 06/14/2007.

Applicant's arguments filed 11/12/2008have been fully considered but they are not persuasive.

Applicants assert that none of the references cited above teach a pharmaceutical composition which is substantially pH independent since they all relate to enteric coatings which are said to be soluble in the small intestine but are not soluble in low pH gastric environment.

The relevance of this assertion is unclear. Since the composition taught by the combination of references is within the same claimed scope of applicants claimed invention it is inherent that the same composition will have the same properties including its dissolution profile within a patient's body. Applicants have not amended their claims in such a way that the composition is materially different than the composition disclosed by the combination of references above.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618